# MDS NEWS HIGHLIGHTS

## FROM THE GUEST EDITOR’S DESK

- **CAR-T THERAPY IN MDS**  
  **Presented by:** David A. Sallman, MD  
  Assistant Member in the Department of Malignant Hematology at Moffitt Cancer Center, Tampa, Florida

## PLAN TO ATTEND

**ASH 2021: MDS FOUNDATION VIRTUAL SYMPOSIUM**  
December 10, 2021, Atlanta, Georgia

**16TH INTERNATIONAL CONGRESS ON MYELODYSPLASTIC SYNDROMES**  
September 23-26, 2021, Toronto, Canada

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www.mds-foundation.org
CAR-T THERAPY IN MDS

David A. Sallman, MD
Assistant Member in the Department of Malignant Hematology at Moffitt Cancer Center, Tampa, Florida

INTRODUCTION

The standard of care therapy for patients with higher risk myelodysplastic syndromes (HR-MDS) are the hypomethylating agents (HMAs) azacitidine and decitabine. However, only 40–50% of patients will achieve a response and even in responding patients, the median duration of treatment for HMA therapy is <12–18 months and nearly all patients will ultimately progress. For HR-MDS patients who fail HMA (i.e. relapse after initial response or refractory), outcomes are dismal with a median overall survival of <6 months. To further refine prognostication in the HMA failure setting, a prognostic score utilizing 6 variables (i.e. age, Eastern Cooperative Oncology Group (ECOG) performance status, bone marrow blast counts, cytogenetics, platelet counts, and red blood cell (RBC) transfusion-dependency) was developed and independently validated although even in the low-risk group, survival was still <12 months.

TREATMENT OPTIONS FOR HMA FAILURE MDS

Together, the HMA failure MDS group represents the highest unmet need for patients with MDS and has been previously reviewed. To date, many agents, particularly HMA combinations, have failed to achieve reproducible or durable responses in this patient group, although recent data have shown that the addition of the BCL-2 inhibitor venetoclax to HMA therapy holds some promise. One significant challenge in MDS patients versus patients with acute myeloid leukemia (AML), is that mutations that can be specifically targeted (e.g. FLT3 and IDH 1/2 mutations) are very rare in MDS patients. Given these challenges and the unmet need, investigation of novel immunotherapies in order to offer new treatment options for patients is warranted. Notably, the development of chimeric antigen receptor (CAR) T-cell therapy has brought forth a paradigm change in the management of B-cell hematologic malignancies and is being actively investigated in myeloid malignancies. The following sections will highlight the challenges of CAR T-cell development in MDS/AML patients, ongoing strategies and lastly offer some insight in the future direction of these therapies for our patients. As preclinical models for MDS are significantly lacking versus AML, many of the initial strategies have focused on AML patients although there is a high degree of overlap between these diseases, particularly with current antigen targets to date. However, future research is warranted to focus on MDS patients in particular. From a disease perspective, the non-proliferative nature of an MDS patient’s disease may make this group optimal from a clinical perspective for immuno-oncology (IO) based approaches.

CAR-T THERAPY FOR MDS/AML PATIENTS

CARs are synthetic proteins able to re-create antigen binding and T-cell activation. Gene modification of a T-cell with a CAR ultimately results in the surface expression of a novel receptor which allows the T-cell to recognize the antigen that is targeted. Although first generation CARs were not efficacious, 2nd generation CARs have had robust clinical activity in B-cell malignancies via incorporation of a costimulatory domain (predominantly CD28 and 41BB) which leads to improved T-cell activation, persistence and tumor cell killing. Thus, the majority of CAR concepts in MDS/AML patients are with 2nd generation CARs although 3rd (i.e. inclusion of 2 costimulatory domains), 4th (i.e. typically 2nd gen + constitutively expressed or inducible chemokine) and other generations CARs are also in development.

Whereas CD19 is universally expressed in B-cells, there is no uniform antigen to target in patients with MDS and AML. CD123, the transmembrane α chain of the interleukin-3 receptor, is highly expressed on leukemic blasts and leukemic stem cells, although is also expressed on normal hematopoietic cells. Preclinically targeting CD123 in AML models has been shown to be highly effective although also resulted in marrow ablation in some studies. Although these reports have been evaluated in AML models, recent data have highlighted significant expression in MDS stem cells (i.e. CD34+/CD38- cells), with similar expression between HR-MDS and AML. Currently, Amel-01 is a phase 1 clinical trial of a 2nd generation off-the-shelf allogeneic CAR targeting CD123 for AML patients although ideally will also be investigated in MDS patients in the near future. The off-the-shelf component allows for immediate infusion of cells which is clinically very relevant given patients often require urgent therapy whereas traditional CAR-T manufacturing times with ex-vivo expansion is around 3+ weeks. Additionally, allogeneic products are derived from normal T-cells which is advantageous given the functionality of T-cells in relapsed/refractory AML patients may be significantly impaired. With allogeneic products, gene editing technologies are required (e.g. TALEN and CRISPR/Cas) of the endogenous T-cell receptor in order to prevent graft versus host disease. Another challenge with allogeneic products is they can be more rapidly rejected by the host immune system and thus potentially more intensive lymphodepletion could be required. The above CD123 product has gene inactivation of CD52 to allow alemtuzumab, a monoclonal antibody targeting CD52, to be incorporated into the lymphodepletion regimen.

Another primary target in MDS/AML patients to date is CD33, a transmembrane receptor of the sialic acid-binding immunoglobulin-type lectin (SIGLEC) family. Again, preclinical data have validated CD33 as a target in AML models although with...
potential marrow ablation.\textsuperscript{14} A phase 1 clinical trial for MDS, chronic myelomonocytic leukemia (CMML) and AML patients is underway with PRGN-3006 CAR-T cells.\textsuperscript{15} This novel CAR production process also circumvents the typical prolonged production process via a non-viral gene delivery system via electroporation of the Sleeping Beauty plasmid where apheresis to cell infusion can occur in 2 days. Notably, the PRGN-3006 CAR T-cells incorporate membrane bound IL-15 which has been shown to improve the expansion, persistence and ultimately AML killing in pre-clinical models. There are additionally several other CD33 trials that are ongoing for AML patients in both pediatric and adult populations.

Given challenges with non-uniform expression as well as potential off-tumor toxicity, a recent CAR approach has utilized NKG2D, the predominant killing receptor of Natural Killer (NK) cells, as a CAR. Notably, ligands for NKG2D (i.e. MICA/MICB and the ULBP family) are highly expressed on transformed cells with very limited expression on non-malignant cells. This concept is thus potentially agnostic to tumor type although high expression of NKG2D ligands has been shown in MDS/AML patients. In this regard, CYAD-01 is an NKG2D CAR that has been evaluated in phase 1 trials in MDS/AML patients both with and without lymphodepleting chemotherapy.\textsuperscript{16} As proof-of-principle, objective responses have been observed including 1 patient who is now 3+ years from allogeneic stem cell transplantation although largely efficacy has not been durable. Notably, increased responses have been observed in patients with low blast counts further supporting ongoing investigation in MDS. To further improve efficacy and persistence, 2nd generation concepts are ongoing (NCT04167696).

**NOVEL CAR APPROACHES**

Additionally, at least with CD33 and CD123, there is some expression on normal hematopoietic cells. This latter issue could lead to marrow ablation and inability for future hematopoiesis at least in pre-clinical models as discussed above. Given the potential for marrow ablation, the vast majority of concepts require patients to have a backup allogeneic donor, which although would still be a clinically meaningful endpoint of successful bridge to allogeneic stem cell transplantation, the challenge is this criterion excludes many patients. Additionally, there can be “on-target/off-tumor” toxicity where target expression is expressed on non-hematopoietic cells. This has occurred at least with CD123 targeting as manifested by capillary leak syndrome. Based on these issues, CAR-T cells with co-expression of a CAR and a chimeric costimulatory receptor (CAR+CCR) would only eliminate cells that co-express both targets, thereby limiting cytoxicity to double-positive tumor cells and relatively sparing single-positive normal tissues. Large transcriptomics and proteomics datasets from malignant and normal tissues identified potential targets expressed on leukemia stem cells, but not in normal CD34+CD38- hematopoietic cells.\textsuperscript{17} As an example, CD33+CD70 stained >97% of cells in AML samples, while staining <5% of normal HSCs and T-cells. Similarly based on flow cytometry analyses of leukemic stem cell and bulk blast AML populations, Haubner and colleagues identified multiple combinations that could be exploited with this approach such as CD33+CLL1 and TIM-3+CLL1.\textsuperscript{18} Notably, the authors did observe some changes in target expression based on the treatment status of patients (i.e. newly diagnosed versus refractory) and thus in future clinical trials serial analyzing target antigens will be critical to best understand thresholds of expression required and potential biomarkers of response.

One key potential issue with any single antigen targeted CAR (or CAR+CCR approach) is that many patients will have heterogeneous expression of these targets where some blast or leukemic stem cell populations may have weak or complete absence of expression thus significantly limiting the potential clinical efficacy. Thus, a combinatorial CAR approach (i.e. CAR+CAR) would prevent antigen escape but have similar and potentially increased toxicity issues related to above. In concordance with these data, probably the best clinical responses reported to date are with the CD33/CLL1 compound CAR.\textsuperscript{19} Notably, Liu and colleagues reported MRD negative responses in 7 of 9 patients with 6 of the patients being bridged to allogeneic stem cell transplantation. Importantly, 1 of the 2 non-responding patients was negative for one of the target antigens. Of importance, CLL1 is likely a more specific target to leukemic stem cells and of importance a recent case report targeting CLL1 with a 4th generation CAR resulted in a CR that has been durable for 6 months remission and other CLL1 CARs are in development.\textsuperscript{20} One effort to create a truly “leukemic specific” target has been via knocking out CD33 in the hematopoietic stem cell product vis CRISPR models.\textsuperscript{21} Of importance, the authors demonstrated in mouse and primate models that CD33 expression is not required for normal hematopoiesis. Thus, the clinical trial concept would be to engineer both an allo-CD33 CAR and an allo-CD33 knockout stem cell product from a single donor. The patient would ultimately have allogeneic stem cell transplantation with the edited product followed by subsequent infusion of the CD33 CAR to eliminate all CD33 expressing hematopoietic cells. Similar autologous concepts are also being developed. Safety will be a key consideration in these concepts and will also have the challenge of non-uniform expression of CD33 on the AML cells.

**FUTURE DIRECTIONS**

HR-MDS patients, after HMA failure, represent a patient cohort that has the most urgent needs for novel therapeutic strategies. CAR-T holds significant promise albeit with significant potential efficacy and safety issues. Although a majority of the clinical trial concepts have preferentially focused on AML populations, trials are starting to include MDS patients and we eagerly await these initial data. Additional challenges exist based on the significant immunosuppressive micro-environments of patients with myeloid malignancies.\textsuperscript{22} Perhaps combinatorial therapy will be required with both traditional CAR and adjuvant agents targeting the immune system. However, I am optimistic and hopeful that we will eventually have novel IO based approaches for our patients.
REFERENCES


Did You Know?

The Myelodysplastic Syndromes (MDS) Foundation, Inc. was established by an international group of physicians and researchers to provide an ongoing exchange of information relating to MDS. Until the Foundation was set up, no formal working group had been devoted to MDS. Since its inception, we have conducted 15 international symposia in Austria, England, the United States (Chicago, Washington, DC), Spain (Barcelona, Valencia), Czech Republic, Sweden, France, Japan, Italy, Greece, Scotland, Germany, and Denmark. The 16th International Congress will be held in Toronto, Canada on September 23-26, 2021.

A major MDS Foundation effort is our international information network. This network provides patients with referrals to Centers of Excellence, contact names for available clinical trials, sharing of new research and treatment options between physicians, and extension of educational support to physicians, nurses, pharmacists and patients.

In response to the needs expressed by patients, families, and healthcare professionals, we have established patient advocacy groups, research funding, and professional educational initiatives. The MDS Foundation is a publicly supported organization, exempt from federal income tax under section 501(C)(3) of the IRS code.

Learn more about The Myelodysplastic Syndromes Foundation, Inc. and find additional resources here: www.mds-foundation.org
MEETING HIGHLIGHTS AND ANNOUNCEMENTS

THE 63RD AMERICAN SOCIETY OF HEMATOLOGY ANNUAL MEETING AND EXPOSITION 2021 (ASH 2021) WILL TAKE PLACE 11 – 14 DECEMBER 2021 AS A HYBRID EVENT IN ATLANTA, GA, USA AND IN A VIRTUAL FORMAT

VIRTUAL SYMPOSIUM
DECEMBER 10, 2021 • 7AM – 10 AM
MDS 2021: FROM CUTTING EDGE DEFINITION OF DISEASE TO MORE EFFECTIVE TREATMENTS
ATLANTA, GEORGIA

CONTINUING OUR MISSION OF INTERNATIONAL COLLABORATION IN THE FIELD OF MDS

ON BEHALF OF THE MDS FOUNDATION AND OUR BOARD OF DIRECTORS, THANK YOU FOR JOINING OUR 2020 VIRTUAL SYMPOSIUM!
To view our 2020 ASH Virtual Symposium Webinars visit https://www.mds-foundation.org/ash-2020-webinars

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Available in the Google Play Store and iTunes
WELCOME TO MDS 2021

On behalf of the Local Organizing Committee and the MDS Foundation, it is our pleasure to invite you to the 16th International Congress on Myelodysplastic Syndromes taking place in Toronto, Canada from 23-26 September 2021.

As in previous years, the Congress will cover the latest findings in MDS basic and translational research as well as all clinical aspects of MDS diagnosis, prognosis, and management. The main lectures will be delivered by recognized international leaders in the field, and we look forward to including high-level research presentations, selected from the abstracts submitted by colleagues.

As we are currently dealing with many uncertainties around us, major gatherings and travel remain under reservations as well. We want you to know that we are considering different formats to ensure you will be able to attend safely, wherever you are. We will keep you informed of the final decisions around the Congress.

2021 has many unknowns, but one thing is certain: shared knowledge will be the key to moving our field forward. Despite the circumstances, we are focusing our efforts on education and research to improve and advance treatment & patient care, and MDS 2021 will enable the community to meet and make it all happen.

Join us for a vivid congress experience and help us shape the future of MDS!

Rena Buckstein & Karen Yee
Congress Chairs

MAKE AN IMPACT.
SHARE YOUR RESEARCH.

New research findings will be essential in advancing MDS science and patient care in 2021 & beyond. So, we urge you – make a mark with your work and submit an abstract.

Share your knowledge with the community today, so you can shape the future of MDS tomorrow.

ABSTRACT TOPICS INCLUDE:

- Cytomorphology
- Molecular aberrations (cytogenetic, genetic, gene expression)
- Clonal diversity & evolution
- Prognostic factors of outcome and risk assessment
- ARCH, CCUS, ICUS
- MDS in childhood
- Phase II-III Clinical Trials - Allogeneic hematopoietic cell transplantation
- Immunosuppressive therapy - New developments

ABSTRACT SUBMISSION DEADLINE: 11 MAY 2021
SUBMIT YOUR ABSTRACT ONLINE VIA: WWW.MDS.KENES.COM
EARLY BIRD REGISTRATION DEADLINE: 29 JUNE 2021
**THURSDAY, SEPTEMBER 23, 2021**

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<td><strong>Trainee advice session: RNA-seq as a primary diagnostic tool in myeloid malignancies</strong></td>
<td><strong>Trainee advice session: Genomics 101</strong></td>
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<td><strong>Workshop II: Mouse models of MDS</strong></td>
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<td><strong>Trainee advice session: Genomics 101</strong></td>
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<tr>
<td>Stephen Nimer, Rena Buckstein, Karen Yee</td>
<td>Shabbir Alibhai</td>
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<td>MDS today and in 20 years</td>
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<tr>
<td>Luca Malcovati</td>
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<td>Shabbir Alibhai</td>
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**19:30-21:30**

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<td>08:00-09:30</td>
<td><strong>Plenary Session:</strong> BM microenvironment and inflammation</td>
<td><strong>Meet the Expert I:</strong> Optimizing transfusion support for patients with MDS</td>
<td><strong>Meet the Expert II:</strong> Overlap of AA, PNH and LGL</td>
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<td>08:00-08:20 Inflammatory signaling in the pathogenesis of MDS</td>
<td>Yulia Lin</td>
<td>Austin Kulasakaraj</td>
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<td>David Sallman</td>
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<td>09:10 - 09:30 Immune pathogenesis of MDS</td>
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<td>09:30-10:00</td>
<td>Coffee Break, Poster Viewing &amp; Visit the Exhibition</td>
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<td>10:00-11:30</td>
<td><strong>Plenary Session:</strong> Molecular mechanisms of disease and targets</td>
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<td>10:00-10:20 CHIP, CCUC/ICUS as models of clonal progression</td>
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<td>Liran Shlush</td>
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<td>10:20-10:35 Genetic basis for leukemia development</td>
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<td>Ben Ebert</td>
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<td>10:35-10:50 Oral abstract</td>
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<td>10:50-11:10 Lessons from the IWG-PM</td>
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<td>Eli Papaemmanuili</td>
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<td>11:10-11:30 Q&amp;A</td>
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<td>Akiko Shimamura</td>
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<td>13:35 - 13:55 Hereditary predisposition to MDS</td>
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<td></td>
<td>Lucy Godley</td>
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<td>14:00-15:10</td>
<td><strong>Plenary Session: Cellular and immune therapy</strong></td>
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<td>14:00-14:20 Immunotherapy strategies in MDS (vaccines, CAR-T)</td>
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<td>14:35-14:55 Immune checkpoint inhibitors in MDS</td>
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<td>Amer Zeidan</td>
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<td>14:55-15:10 Q&amp;A</td>
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<td><strong>Plenary Session: Low Risk MDS</strong></td>
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<td>15:40-16:00 TGFbeta pathway targeting</td>
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<td>Amit Verma</td>
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<td>16:00-16:20 Management of Low risk disease - now and future</td>
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<td>Uwe Platzbecker</td>
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<td>16:20-16:45 Poster pitches</td>
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<td>16:45-17:00 Q&amp;A</td>
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<td>17:00-19:00</td>
<td><strong>Industry Supported Session</strong></td>
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Posters Viewing & Visit the Exhibition
### SATURDAY, SEPTEMBER 25, 2021

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<thead>
<tr>
<th>Time</th>
<th>Hall A</th>
<th>Hall B</th>
<th>Hall C</th>
<th>Hall D</th>
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<tbody>
<tr>
<td>07:30-08:00</td>
<td></td>
<td>Meet the Expert III: Making heads and tails of NGS printouts and their role in MDS Ben Ebert</td>
<td>Meet the Expert IV: Lenalidomide treatment in MDS Valeria Santini</td>
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<tr>
<td>08:00-09:30</td>
<td><strong>Plenary Session:</strong> Clinical research: targeted agents, prognosis and predictive models</td>
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<td></td>
<td>8:00 - 8:20 What we learn from real-world registries Theo de Witte</td>
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<td></td>
<td>8:20 - 8:45 Debate: Personalized therapy is ready for prime time in MDS Garcia Manero versus Luca Malcovati</td>
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<td></td>
<td>8:45 - 9:00 Oral abstract</td>
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<td></td>
<td>9:00 - 9:20 How machine learning can contribute to prognostic and predictive models Aziz Nazha</td>
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<td>9:20 - 9:30 Q&amp;A</td>
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<td>09:30-10:00</td>
<td>Coffee Break, Poster Viewing &amp; Visit the Exhibition</td>
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<td>10:00-11:45</td>
<td><strong>Plenary Session: High Risk MDS</strong></td>
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<td>10:00 - 10:20 Mechanisms and predictors of drug resistance, intolerance to HMAAs and clinical management strategies in high risk MDS Mikael Sekeres</td>
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<td>10:20 - 10:35 Oral Abstract</td>
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<td>10:35 - 10:55 Strategies to reduce relapse and improve survival post allogeneic stem cell transplant Corey Cutler</td>
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<td>10:55 - 11:10 Q&amp;A</td>
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<td>11:10 - 11:45 Poster pitches</td>
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<td>11:45-13:30</td>
<td><strong>Industry Supported Session</strong> (12:00-13:15)</td>
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<td>Lunch Break, Poster Viewing &amp; Visit the Exhibition</td>
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### SATURDAY, SEPTEMBER 25, 2021 (continued)

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<tr>
<th>Time</th>
<th>Hall A</th>
<th>Hall B</th>
<th>Hall C</th>
<th>Hall D</th>
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<tbody>
<tr>
<td>13:30-14:45</td>
<td><strong>Plenary Session: CMML and the Spliceosome</strong>&lt;br&gt;13:30 - 13:50 Novel therapeutic strategies for CMML&lt;br&gt;Eric Padrón&lt;br&gt;13:50 - 14:05 Oral abstract&lt;br&gt;14:05 - 14:25 The cutting edge of the spliceosome&lt;br&gt;Matt Walter&lt;br&gt;14:25 - 14:40 Q&amp;A</td>
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<td>14:40-15:00</td>
<td>Short Break</td>
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<tr>
<td>15:00-16:00</td>
<td><strong>Plenary Session: Difficult Clinical Cases</strong>&lt;br&gt;15:00 - 15:15 Thrombocytopenia in low risk MDS&lt;br&gt;Valeria Santini&lt;br&gt;15:15 - 15:30 Low risk disease with high risk mutation&lt;br&gt;Moshe Mittelman&lt;br&gt;15:30 - 15:45 Fit 72 yo with MDS-EB-2 (17% blasts) - induce and transplant, HMA and transplant, HMA alone&lt;br&gt;Ari Gagoundis&lt;br&gt;15:45 - 16:00 75 yo with SD on HMA after 6 cycles but remains pancytopenic and transfusion dependent&lt;br&gt;Michael Savona</td>
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<tr>
<td>16:00-16:50</td>
<td><strong>Plenary Session: Disease Progression Biology</strong>&lt;br&gt;16:00 - 16:20 Insights from the MDS transcriptome&lt;br&gt;Jackie Boulterwood&lt;br&gt;16:20 - 16:35 Oral abstract&lt;br&gt;16:35 - 16:50 Q&amp;A</td>
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<tr>
<td>19:30 - 21:30</td>
<td>Networking dinner</td>
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### SUNDAY, SEPTEMBER 26, 2021

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>08:00-09:20</td>
<td><strong>Plenary Session: Clinical</strong></td>
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<td><strong>8:00-8:40 What should be the clinical targets of iron chelation</strong></td>
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<td><strong>therapy</strong></td>
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<td><strong>Heather Leitch</strong></td>
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<td><strong>8:40-9:20 Debate: Is therapy-related MDS always a poor</strong></td>
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<td><strong>prognosis: Biology and diagnosis?</strong></td>
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<td><strong>Michael Houser</strong></td>
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<td><strong>Is therapy-related MDS always a poor prognosis: Treatment?</strong></td>
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<td><strong>Pierre Fenaux</strong></td>
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<tr>
<td>09:20-10:00</td>
<td><strong>Coffee Break, Poster Viewing &amp; Visit the Exhibition</strong></td>
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<tr>
<td>10:00-11:00</td>
<td><strong>The Tito Bastianello and MDSF Young Investigators Awards</strong></td>
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<tr>
<td>11:00-11:45</td>
<td><strong>Greatest hits from this meeting</strong></td>
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<td><strong>Reena Bickstein, Karen Yee, Andre Schuh</strong></td>
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<tr>
<td>11:45-12:00</td>
<td><strong>Closing Ceremony</strong></td>
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REGISTRATION

Registration fees [in CAD$] apply to payments received prior to the indicated deadlines.

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<tr>
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<td>Until June 29, 2021</td>
<td>June 30 - August 24, 2021</td>
<td>From August 25, 2021</td>
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<tr>
<td>MDSF member*</td>
<td>CAD $ 880</td>
<td>CAD $ 1,050</td>
<td>CAD $ 1,175</td>
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<tr>
<td>Non member</td>
<td>CAD $ 1,050</td>
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<td>Hematologists in training **</td>
<td>CAD $ 750</td>
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<td>Nurse**</td>
<td>CAD $ 350</td>
<td>CAD $ 420</td>
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<td>Student**</td>
<td>CAD $ 175</td>
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<td>Workshop</td>
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* In order to become a member of the MDS Foundation and benefit from reduced fees, please visit the MDSF Membership website.
** In order to benefit from the special fee, a submission of your status confirmation [approval letter signed by the Head of Department or copy of your status ID] must be uploaded during online registration.
*** The Workshops have limited availability and registration is on a first-come first-serve basis.

FEES FOR ALL MEETING PARTICIPANTS INCLUDE

- Participation in all scientific sessions
- Entrance to the Exhibition
- Invitation to the Opening Ceremony & the Welcome Reception
- Coffee & lunch during breaks, as indicated in the program
- Printed material of the Symposium
- Certificate of attendance

PAYMENT METHODS

Payment of registration fees must be made in CAD after completing the registration process. You may choose one of the following methods:

Credit Cards: i.e. Visa, MasterCard or American Express
Bank Transfer: Additional CAD 30 handling fee is required.
Please make drafts payable to:

MDS 2021 Congress, Toronto
Credit Suisse Bank, Geneva Branch, 1211 Geneva 70, Switzerland
Clearing number: 4835
Account number: 1500934-92-270
Swift code: CRESCHZH60A
IBAN number: CH97 0483 5150 0934 9227 0

- Outstanding payments will be collected on-site and charged the on-site rate. A copy of the bank transfer [or other proof of payment] will be required in the event that registration fees were not credited to the Conference account on time.

CANCELLATION POLICY

All cancellations must be emailed to reg_mds21@kennes.com prior to the below deadlines. Refund of the registration fee will be as follows:

- Cancellations received up to and including June 30, 2021 – full refund
- Cancellations received from July 1 until September 6, 2021 – 50% refund
- From September 7, 2021 – no refund will be made

Note, in case of cancellation at any stage, the Bank Transfer handling fee (CAD 30) will not be refunded – applicable to Bank Transfer payments only.

GROUP REGISTRATION

For group registration of 10 delegates or more, companies are requested to contact the MDS Registration Team at:
reg_mds21@kennes.com

GUEST ATTENDANCE POLICY

All event activities [including educational sessions, meal functions, exhibition hall, etc.] are exclusively reserved for registered attendees. Non-registered guests [including children, family members, colleagues, etc.] are not allowed in any of the event areas. Badges provided at registration are required for entrance into all functions and will be strictly enforced.
LATEST NEWS REGARDING THE MOLECULAR MUTATION PROJECT OF THE IWG-PM

IWG-PM/MOLECULAR PROJECT

In patients with MDS, TP53 mutations associate with high-risk presentation, complex karyotype, acute myeloid leukemia (AML) progression and poor response to hematopoietic stem cell transplantation. These findings highlight the relevance of TP53 as a prognostic and predictive biomarker. Despite the central role of TP53 in MDS, the clinical implications of TP53 mutations in the context of allelic state have not been extensively studied. Under the auspices of the International Working Group for Prognosis in MDS Molecular project (IWG-PM/Molecular) investigational efforts generated data from which an abstract was presented at the ASH 2019 meeting describing results obtained from sequencing marrow or blood samples from a representative cohort of 3,324 peri-diagnosis MDS patients on a next generation sequencing (NGS) panel along with a validation cohort from a Japanese MDS sample compendium.

Data analysis of this study segregated patients into two TP53 states: a mono-allelic state where one wild type allele remained (33% of TP53 mutated patients, n=126); and a multi-hit state where TP53 was altered multiple times by either mutations, deletions or cnLOH (67% of TP53 mutated patients, n=254). The findings demonstrated that TP53 allelic state was associated with clinical presentation and outcomes. Mono-allelic TP53 mutation patients presented with more favorable disease than multi-hit TP53 mutated patients. These findings indicated that TP53 status is a critical candidate for incorporation into molecularly informed risk stratification schemas (molecular IPSS-R). Thus, TP53 mutation state is important for MDS risk estimation, disease monitoring and future correlative research.

SF3B1 MUTATED MDS AS A DISTINCT DISEASE SUBTYPE PROJECT

A large body of evidence indicates that in MDS, the SF3B1 mutation is closely associated with ring sideroblasts and ineffective erythropoiesis and is characterized by less aggressive clinical course. The available evidence supports recognition of SF3B1-mutant MDS as a distinct nosologic entity. To further validate this, Dr Malcovati and colleagues interrogated the dataset of the IWG-PM. Based on these findings, the following diagnostic criteria for the MDS with mutated SF3B1 was proposed as a distinct MDS subtype: (i) cytopenia defined by standard hematologic values; (ii) somatic SF3B1 mutation; (iii) isolated erythroid or multilineage dysplasia; (iv) the presence of any ring sideroblasts; (v) bone marrow blasts <5% and peripheral blood blasts <1%.

IWG-PM: THERAPY-RELATED MDS PROJECT

In the current WHO classification, therapy-related Myelodysplastic Syndromes (t-MDS) are placed together with therapy-related Acute Myeloid Leukemia (t-AML) and Myeloproliferative Neoplasms (t-MPN) into one subgroup (t-MN) independent of morphological or prognostic features. Drs. Kuendgen, Nomdedue, Tuechler and colleagues have assembled a database including 2087 t-MDS patients from different international MDS groups to evaluate current classification and prognostic tools. They analyzed and compared 1245 t-MDS patients to 4593 primary MDS (p-MDS) patients represented in the IWG-PM database. These data demonstrated that the IPSS-R and WPSS-R separated t-MDS patients into differing risk groups effectively and indicated that all established prognostic risk factors for p-MDS maintained relevance for t-MDS, with cytogenetic features having enhanced predictive power. Poorer clinical outcomes occurred in each t-MDS compared to those from p-MDS subgroups. Despite t-MDS being considered as having a uniformly poor prognosis these data demonstrated differing outcomes for each t-MDS subgroup. Given these data, these findings suggest the ability and need for classifying t-MDS as a separate entity and distinct from the other WHO classified t-myeloid neoplasms (t-MNs). Application of this terminology would enable more reasonable treatment decisions and facilitate the inclusion of t-MDS patients into clinical studies.
REFERENCES


2. Papaemmanuil E, Classification and personalized prognosis in MDS. MDS Foundation Symposium, ASH meeting, 2019 Orlando, December.


This global project is being coordinated by Ben Ebert and Peter Greenberg (co-Chairs), Rafael Bejar and Ellie Papaemmanuil, with statistical support by Donna Neuberg, Kristin Stevenson and Heinz Tüchler.
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Chicago, Illinois, United States
This year marks our 27th year since the MDS Foundation was established to promote the ongoing exchange of information relating to MDS.

How far we have come!

In these years we have developed a vital network of MDS Centers of Excellence; hosted 15 International Congress meetings to educate healthcare professionals on the latest scientific developments in MDS; supported young investigators with grants to further research in MDS; developed and revised the International Prognostic Scoring System to better classify and treat patients with MDS; and worked diligently to support and educate patients and their families as they travel through their MDS journey.

The research into MDS, AML, and MPNs has grown, with more professionals dedicated to these diseases than ever before. We continue to learn more about the biology of these diseases and to develop the tools needed to understand related diseases, including clonal hematopoiesis. We continue our efforts to prevent early stages of these diseases from developing into more serious stages and to have new therapies and more hope for patients and families battling these diseases. The strength of the MDS Foundation is made possible due to the incredible patients, caregivers, family members, healthcare providers, researchers, supporters, and partner organizations we are honored to work with every day. The MDS community is strong and growing stronger thanks to continued advances in research and treatment.

Thousands worldwide depend on the MDS Foundation for information, education, and empowerment. Given the dedication and strength of our ever-growing community, we are proud to continue to lead the way and provide support for this community for years to come.

Tracey Iraca & Stephen Nimer, MD
During these unprecedented times, while the MDS Foundation remains closed, we have remained fully operational remotely from home. During these difficult days, we want to assure you that we are active and working hard to help our MDS patients, their families, and the entire MDS community.

The spread of the coronavirus has created a very stressful environment for all, and especially for those living with MDS.

Keeping yourself and others safe during the pandemic is especially important for those who already have compromised immune systems. The Centers for Disease Control and Prevention (CDC) says the virus is thought to be spread mainly from person to person between people who are in close contact with each other. Respiratory droplets from a person with COVID-19 can be spread through coughing, sneezing or talking. When out in public, people are encouraged to wear face masks or cloth masks.

DO YOU NEED A MASK OR BUFF?
Contact Dee via email at: dmurray@mds-foundation.org or call the office at 1-800-637-0839.

FIND THE TRUSTED RESOURCES YOU NEED...
You or someone you know has been diagnosed with MDS

Hearing the words Myelodysplastic Syndromes or MDS can be frightening. The diagnosis of MDS is often unexpected and filled with both immediate and long-term challenges. You probably have many questions. Have you accessed your complete set of tools to prepare, participate, and LIVE with MDS?

Dealing with MDS can be very difficult, but it helps to have resources that are reliable and easy to understand.

To order your FREE copy of our resources available in multiple languages, please visit our website: https://www.mds-foundation.org/material-order-form-4
**HISTORY OF MDS & THE MDS FOUNDATION**

**TIMELINE OF MDS HISTORY**

### EARLY

**1970’s**
- Creation of the Cooperative Leukemia Diagnostic (CLD) Working Group by the FAB Cooperative Leukemia Group

**1976**
- CLD Working Group identified RAEB & CMML - These two disorders were subtypes of Dysmyelopoietic Syndromes

**1982**
- FAB renamed these disorders Myelodysplastic Syndromes with 5 subtypes identified.

**1988**
- 1st International Symposium on MDS in Innsbruck, Austria

**1991**
- 2nd International Symposium on MDS in Bournemouth, UK

**1994**
- MDS Foundation, Inc. established
- 3rd International Symposium on MDS in Chicago, IL, USA

**1997**
- Inception of the MDS Center of Excellence Program
- Development of the International Prognostic Scoring System (IPSS)
- 4th International Symposium on MDS in Barcelona, Spain

**1999**
- 5th International Symposium on MDS in Prague, Czech Republic

**2000**
- Inception of the MDSF Young Investigator Grant Program

**2001**
- 6th International Symposium on MDS in Stockholm, Sweden
- WHO Classification of MDS

**2003**
- 7th International Symposium on MDS in Paris, France

**2004**
- FDA Approval of Vidaza (azacitidine) - 1st treatment for MDS

**2005**
- 8th International Symposium on MDS in Nagasaki, Japan
- FDA Approval of Exjade for Iron Overload
- FDA Approval of Revlimid (lenalidomide)

**2006**
- 9th International Symposium on MDS in Florence, Italy
- FDA Approval of Dacogen (decitabine)

**2007**
- MDSF International Nurse Leadership Board (NLB) is established
- International Working Group for the Prognosis in MDS (IWG-PM) is established

**2008**
- 10th International Symposium on MDS in Patras, Greece

**2009**
- Inception of the MDSF Young Investigator Grant Program
JOIN THE MOVEMENT in 2021

Join your local Move for MDS community walk, raise funds and show support to the Myelodysplastic Syndromes Foundation in our fight against MDS. Our year-round events increase awareness of this rare disease and accelerate critical research.

Dates & Locations

**PACIFIC NORTHWEST** (Virtual)
Date: June 12, 2021

**CALIFORNIA: LA, SD & SF** (Virtual)
Date: June 13, 2021

**CHICAGO** (Virtual)
Date: June 26, 2021

**MANHATTAN** (In Person)
Target Date: October 2nd or 3rd, 2021
Target Location: Battery Park City

**BOSTON** (In Person) | **GLOBAL** (Virtual)
Target Date: October 24, 2021 (In honor of MDS World Awareness Day)
Target Location: Boston Common

For more information visit MoveForMDS.com
HIGHLIGHTS OF LATEST LITERATURE IN MDS

SUNEEL D. MUNDEL, PHD
RHEA MUNDEL

Listed below are citations of some new publications relevant to MDS (pathogenesis, clinical characterization, management, etc.). To access the complete articles log on to www.pubmed.gov.

EPIDEMIOLOGY, DIAGNOSIS AND PROGNOSIS:


Fourteen randomized trials with a total of 5739 patients with solid tumors were the subject of this pooled incidence rate ratio (IRR) analysis for MDS/AML cases post PARP-inhibitor treatment. Generally, the risk of MDS/AML post PARP-inhibitor therapy was not elevated as compared to control arm treatments (IRR=1.32). However, when assessed in studies with front-line treatment only, the risk was clearly evident (IRR=5.43). Also, the risk of MDS/AML post PARP-inhibitor therapy was not elevated as compared to control arm treatments (IRR=0.83), while studies including broader patients did show the risk (IRR=2.43).


A population based study using the Dutch province HemoBase registry of 291 MDS patients diagnosed between 2005 and 2017 with a f/u till 2019 showed that, the overall survival (OS) was better for patients with Charlson Comorbidity Index (CCI) <4, age <65 yrs, female sex and low-risk disease. Therapy related and secondary MDS were associated with worse OS as compared to de novo MDS (HR=1.51, p=0.04). Patients in remission at the time of MDS diagnosis, after therapy for prior malignancy, showed comparable OS to de novo MDS (25.5 mo vs 28.3 mo).


The study systematically examined the differences between western versus Asian MDS patients over last 20 years with respect to epidemiological, clinical, biological and genetic characteristics. Asian cases tended to be lower in incidence, almost 10 years younger at the disease onset, and diagnosed with int- to high-risk MDS (vs higher proportion of low risk MDS diagnoses in western population). Also, while the common genetic anomalies among western patients were del(5q), mutations in TET2, SF3B1, SESF2 and IDH1/2 , in Asian patients trisomy 8, del(20q), U2AF1 and ETV6 mutations were more common. Despite these differences, within each individual prognostic category, the OS was comparable between western and Asian patients.

TREATMENT:

RBC Transfusion and Growth Factors:


Elevated serum EPO levels were observed in MDS patients as compared to healthy individuals (p<0.01). However, the difference in sEPO between low versus high-risk patients was not significant. sEPO levels correlated negatively with Hb levels and bone marrow blast counts in high risk patients. Also, an inverse correlation was seen between sEPO and sTNF in low-risk patients.

IMiDs:


A total of 195 non-del(5q) low risk patients with low probability of response to erythropoietin therapy (based on sEPO levels and/or prior erythropoietin treatment), were randomized to receive a
combination of LEN+EPO alfa (n=99) or LEN alone (n=96). After 4 cycles, Major erythroid response (MER) was higher with the combination (28.3%, p=0.004) vs LEN alone (11.5%). At 16 wks too, the MER and overall erythroid response were higher with combination (38.9%/46.5% respectively) vs LEN monotherapy (15.5%/32.3% respectively). Lastly, the MER observed with the combination was also more durable versus LEN monotherapy (23.8 mo vs 13 mo).

Hematopoietic Stem Cell Transplant:
AML/MDS patients (18-65 yr age) with <5% marrow myeloblasts were randomized between myeloablative conditioning (MAC, n=135) and reduced-intensity conditioning (RIC, n=137) prior to receiving hematopoietic cell transplant (HCT) from HLA-matched donor. Median f/u was 51mo. At four years, treatment related mortality was higher in MAC (approx. 25%) compared to RIC (approx. 10%, p<0.001). On the other hand, relapse rate was significantly higher in RIC vs MAC (HR-4.06, p<0.001). At 3 years, the post-relapse survival rate was comparable between MAC and RIC (approx. 25%). The OS upon long term f/u though, was superior with MAC versus RIC (HR-1.54, p=0.03).

Hypomethylating Agents:
A literature meta-analysis of prospective studies published between Jan 1990 and Jul 2020 compared different dosing regimens of two hypomethylating agents, azacitidine and decitabine in lower-risk MDS. No differences were noted between regimens of individual agents or between two agents with respect to response rates and OS. Safety profile too did not have significant differences besides decitabine (20 mg/m²/day x 3 days) showing higher rates of Grade 3/4 anemia and lower rates of diarrhea/constipation. The transfusion independence rate was higher with AZA (75 mg/m²/day x 7 day; p<0.025).
Lower risk MDS patients were randomized to receive CC-486 300 mg/day for 21 days in a 28 day cycle (n=216) or placebo. The RBC transfusion-independence (TI) rate, and median duration of TI were higher in CC-486 treated patients (31%, and approx. 11 mo) versus the placebo group (11%, p=0.0002, approx. 5 mo). The rate of patients with >1.5 mg increase in HB and the rate of platelet improvement were higher in CC-486 treated patients (23.4% vs 4.6% and 24.3% vs 6.5%). Furthermore, although overall death rate was similar in the two arms, the number of deaths in the first 56 days were higher in the treatment arm primarily due to infections in patients with notable pretreatment neutropenia (n=16) vs placebo (n=6).
This Italian registry study of 402 consecutively enrolled MDS patients showed that while 80% patients discontinued due to primary or adaptive resistance, 20% were responsive to AZA at treatment discontinuation. Among the latter, those who subsequently received hematopoietic stem cell transplant, had significantly improved survival. Furthermore, when assessed with North American MDS Consortium scoring system (n=278), the low-risk patients showed better survival vs high-risk patients (p<0.001) regardless of whether they received best supportive care (5 mo vs 2 mo respectively) or active treatment including transplant (16 mo vs 8 mo).
This retrospective analysis of a total of 72 patients (AML, n=65 and MDS, n=7), treated with a combination of venetoclax and hypomethylating agent showed CR/Cri in 53.8% newly diagnosed AML, and in 38.5% relapsed/recurrent AML. The responders to combination were enriched for TET2, IDH1 and IDH2 mutations, while non-responders showed enrichment for FLT3 and RAS mutations. Approx. 59% patients developed infections, and approx. 47% had neutropenic fever.
PATHOBIOLOGY:
1. Fang H, et al. Myelodysplastic syndrome with t(6;9)(p22;q34.1)/DEK-NUP214 better classified as acute myeloid leukemia? A multicenter study of 107 cases. Mod Pathol, 2021; Feb 8 [Online ahead of print]. [https://doi.org/10.1038/s41379-021-00741-w]

Contrary to the prior suggestion in literature to regard MDS with t(6;9)(p22;q34.1)/DEK-NUP214 as AML, when this study compared clinico-pathological features of 107 cases (33 MDS and 74 AML) with this genetic anomaly, the MDS cases tended to be older, had significantly lower WBC, lower blast count in blood and marrow, higher platelet count and a lower frequency of FLT3-ITD mutation. Multivariate analyses showed that initial diagnosis of MDS vs AML and allogeneic hematopoietic stem cell transplant were prognostic for overall survival (p=0.008 and p<0.0001 respectively) underscorign the distinct nature of MDS cases vs AML.


Both Erythroferrone (ERFE) and growth/differentiation factor 15 (GDF15), the regulators of iron homeostasis in erythroid progenitors, were studied in 111 MDS patients. Both showed prognostic value independent of the IPSS-R risk category. ERFE overexpression in low-/int-1 patients predicted superior OS. Also, although ERFE expression was increased in patients with SF3B1 mutations, it predicted OS regardless of SF3B1 mutant or wild type status.

LITERATURE HIGHLIGHTS


This phase Ib/II study assessed a small molecule APR-246 which restores wild-type p53 function. This novel compound was used in combination with azacitidine in 55 patients with at least one TP53 mutation (40 MDS, 11 AML, 4 MDS/MPN). The response among all patients/MDS/AML patients included, ORR-71%/73%/64%, CR-44%/50%/36% respectively. The responding patients showed lowered p53 expression with 38% achieving molecular remission and OS of 14.6 mo compared to 7.5 mo in non-responding patients (p=0.0005). Common adverse events for the combination were febrile neutropenia (33%), leukopenia (29%) and neutropenia (29%).


Both Erythroferrone (ERFE) and growth/differentiation factor 15 (GDF15), the regulators of iron homeostasis in erythroid progenitors, were studied in 111 MDS patients. Both showed prognostic value independent of the IPSS-R risk category. ERFE overexpression in low-/int-1 patients predicted superior OS. Also, although ERFE expression was increased in patients with SF3B1 mutations, it predicted OS regardless of SF3B1 mutant or wild type status.


A special thanks to Suneel and Rhea Mundle for their great efforts in monitoring these important MDS peer-review publications.
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BENEFITS OF MEMBERSHIP:
- MDSF CoEs form the referral base for the patients who contact the Foundation daily.
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- The work of your institution can be shared with our patient and professional contacts via our website and/or our social media channels. We can spread the word of your clinical trials, research projects, etc.

Would you like your treatment center to become part of the referral system for MDS patients and be designated as a Center of Excellence?

To be recognized as a Center of Excellence, an institution must have the following:
- An established university (or equivalent) program
- Recognized morphologic expertise in MDS
- Available cytogenetics and/or molecular genetics
- Ongoing research, including Institutional Review Board–approved clinical trials
- Documentation of peer-reviewed publications in the field

Please contact the Foundation for further information and an application form for your center. The following centers have qualified as MDS Centers of Excellence:

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DO YOU KNOW YOUR MDS SUBTYPE, IPSS-R SCORE AND GENE MUTATION PROFILE?

MDS treatment is individualized based on a patient’s subtype, IPSS-R score and, to some extent, genetic mutation. This knowledge will empower patients and their caregivers to take a more active role in decisions about their treatment and advocate for appropriate treatments that may prolong their life and improve their quality of life. The following infographics are designed to help you begin to understand how your subtype and IPSS-R score are determined, as well as general information on genetic mutations commonly found in MDS and the importance of genetic testing for these mutations.

View our Knowledge is Power website https://www.mdsknowledgeispower.com for more information.

Knowing your subtype, IPSS-R score and gene mutation profile will help facilitate discussions with your healthcare provider on what this means for you personally and help select the best treatment options.

The Revised International Prognostic Scoring System (IPSS-R) is used to estimate life expectancy for a patient newly diagnosed with MDS without treatment and to estimate the risk of developing acute myelogenous leukemia (AML).

A bone marrow biopsy and aspirate, cytogenetics and peripheral blood counts are used to determine your risk category (Very Low, Low, Intermediate, High, Very High).

**CYTOGENETICS**
Cytogenetics is the study of the structure and function of the chromosomes. Long strings of DNA are coiled up with proteins to form the chromosomes. Cytogenetic testing is viewing chromosomes under a microscope to determine if there are any changes in the chromosomes (chromosomal abnormalities).

**BONE MARROW BLASTS**
Blasts are immature blood cells that do not function properly.

**HEMOGLOBIN**
Hemoglobin (Hgb) is a large iron-containing protein in red blood cells that gives blood its red color and carries oxygen from the lungs to all body tissues.

**PLATELETS**
Platelets (Pits) are tiny blood cells that help your body form clots to stop bleeding.

**ABSOLUTE NEUTROPHIL COUNT**
Absolute Neutrophil Count (ANC) is a measure of the number of neutrophil granulocytes present in the blood. Neutrophils are a type of white blood cell that fights against infection.
KNOWLEDGE IS POWER

WHO MDS CLASSIFICATION SUBTYPES

MDS WITH SINGLE LINEAGE DYSPLASIA (MDS-SLD)
Is a low number of one to two types of blood cells in the bloodstream and one type of blood cell looks abnormal (dysplasia) in the bone marrow. For the affected cell type, at least 10% of the cells look abnormal (dysplasia). Less than 5% of cells in the bone marrow are blast (immature) cells with no blasts in the bloodstream.

MDS WITH MULTILINEAGE DYSPLASIA (MDS-MLD)
Is a low number of one or more types of blood cells in the bloodstream and two or more types of blood cells look abnormal in the bone marrow. Of the affected cell types, at least 10% of the cells look abnormal. Less than 5% of cells in the bone marrow are blast cells with no blasts in the bloodstream.

MDS WITH RING SIDEROBLASTS (MDS-RS)
Is a low number of one or more types of blood cells in the bloodstream and bone marrow. At least 15% of young red blood cells in the bone marrow show rings of iron called ring sideroblasts (or at least 5% of the cells also have a mutation in the SF3B1 gene). Less than 5% of cells in the bone marrow are blast cells. There are 2 types with:
MDS-RS and Single Lineage Dysplasia (MDS-RS-SLD): same characteristics as MDS-SLD but with ring sideroblasts
MDS-RS and Multilineage Dysplasia (MDS-RS-MLD): same characteristics as MDS-MLD but with ring sideroblasts

MDS WITH EXCESS BLASTS (MDS-EB)
Is a low number of one or more types of blood cells in the bloodstream that also look abnormal in the bone marrow with an increased number of blast (immature) cells.
MDS-EB1: less than 5% of cells in the bloodstream are blasts. In the bone marrow, 5-9% of cells are blast cells.
MDS-EB2: 5-19% of cells in the bloodstream are blast cells and 10-19% of cells in the bone marrow are blast cells.

PROVISIONAL ENTITY: REFRACTORY CYTOPENIA OF CHILDHOOD (RCC)
Is characterized by persistent cytopenia with less than 5% blasts in bone marrow and less than 2% blasts in the bloodstream. It is the most common subtype of childhood MDS.

MDS WITH ISOLATED DEL(5q)
Is identified when part of chromosome 5 is missing (deleted), this change is called del (5q). One additional chromosome abnormality is also permitted as long as it does not involve chromosome 7. There is a low number of red blood cells in the bloodstream and the number of platelets is normal or high. There is dysplasia in at least one cell type in the bone marrow and less than 5% of the cells are blast (immature) cells.

MDS UNCLASSIFIABLE (MDS-U)
Is when the features of the blood and bone marrow don’t fit any of the other subtypes. One or more types of blood cells are low in the bloodstream, but less than 10% of that cell type may look abnormal in the bone marrow. Very few or no blast (immature) cells are found in the bloodstream on at least 2 occasions and less than 5% of the cells in the bone marrow are blasts. Sometimes the diagnosis is made solely based on the presence of a typical chromosome abnormality that is linked with MDS.

*The subtypes are based on the 2018 WHO Classification System. If you were classified under the 2008 WHO System (RA, RCUD, RARS, RCMD, RCMD-RS, RAEB-1, RAEB-2) your corresponding 2018 classification subtype is:

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<th>2008 Classification</th>
<th>2018 Classification</th>
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<td>5q (5q minus) Syndrome</td>
<td>MDS with isolated del(5q)</td>
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<td>Unclassified MDS</td>
<td>MDS-U (MDS, unclassifiable)</td>
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KNOWLEDGE IS POWER
KNOW YOUR MDS MUTATION

A GUIDE TO GENETIC MUTATIONS

Your doctor may have ordered a DNA sequencing study to identify mutated genes in your MDS cells. This test can help confirm your diagnosis and provide information about which subtype of MDS you have. Some mutated genes are associated with lower risk disease while others may indicate greater risk. Mutations can potentially identify effective therapies to treat your disease.

CHROMOSOME
Chromosomes are structures within cells that contain a person’s genes. Every person has 46 chromosomes. Each chromosome contains thousands of genes.

GENE
Genes, contained in chromosomes, are segments of deoxyribonucleic acid (DNA) that contain the code for making a specific protein that functions in one or more types of cells in the body.

MUTATIONS
Mutations occur when a gene is damaged and alters the genetic message.

DISCUSS MUTATIONS WITH YOUR DOCTOR
Knowing which genetic mutations are present in your MDS cells will open discussions with your healthcare provider about individualized risk assessment and treatment.

GENETIC PROFILES CHANGE OVER TIME
Your profile may change over time therefore it is important to re-characterize MDS at points of progression.

SOME MUTATED GENES IMPACT MDS PROGRESSION
Clinical trials are exploring the potential benefits of targeting genes known to cause and promote MDS. In some cases, the production of abnormal cells can be interrupted.

HOW ARE MUTATIONS IDENTIFIED
Genetic mutation profiles are identified by sequencing the DNA using a bone marrow or blood sample.

COMMONLY MUTATED MDS GENES

| SF3B1 | IDH1 | DNMT3A | TET2 | IDH2 | ASXL1 | TP53 | RUNX1 | SRSF2 | U2AF1 |

Have you checked out our latest module for our “You and MDS” Animated Video series, Understanding Erythropoiesis, yet?

UNDERSTANDING ERYTHROPOIESIS

This animation explains erythropoiesis, which is the term for the production of red blood cells. Red blood cells, called erythrocytes, carry oxygen around your body. This animation explains the erythrocyte life cycle and describes how a low red blood cell count causes anemia. Anemia typically results from bleeding, red blood cell destruction, or decreased red blood cell production in the bone marrow, as seen in disorders such as myelodysplastic syndromes (MDS). The animation describes treatments for a low red blood cell count, including medications, blood transfusions, and stem cell transplant.
BECOME A MEMBER OF THE MDS FOUNDATION COMMUNITY

GET ACCESS TO PATIENT ADVOCACY SERVICES AND SUPPORT THE MISSION OF IMPROVING THE LIVES OF PATIENTS WITH MYELODYSPLASTIC SYNDROMES.

This year nearly 90,000 people will be told they have MDS worldwide – 12,000 to 18,000 newly diagnosed MDS patients in the United States alone. The MDS Foundation, Inc. is working hard to support these patients and the loved ones who care for them.

We are asking for your membership support in our global efforts to change the outcomes of MDS.

WE ARE HERE FOR YOU...

AT YOUR TIME OF DIAGNOSIS

WITH SPECIALIST REFERRALS

THROUGHOUT YOUR CARE

COMING TOGETHER FOR A CURE

JOIN US TO PROMOTE MDS AWARENESS & ADVOCACY

SUPPORT YOUR LOVED ONES
**BENEFITS OF MEMBERSHIP**

- You are part of the solution to change MDS outcomes. Your membership fee helps support global physician and patient educational initiatives, drive research, and helps to empower patients with courage and hope.
- Updates on the status of our Global Centers of Excellence and their live patient and family forum events that allow for more rapid dissemination of new research and treatment developments.
- Information on the latest clinical trials to potentially share or participate in.
- Access to MDS awareness materials to share with family, friends and your primary care physician.
- Opportunities to participate in or host support group events with your friends and community.
- Receive an MDSF Membership Packet including printed educational resources, MDSF masks and wristbands.

**HOW DOES YOUR MEMBERSHIP HELP?**

**$35**  
**Join The Community** (includes benefits listed above)

**$70**  
**Share Hope**  
Also includes a membership scholarship for a patient or caregiver in need.

**$250**  
**Change the Future of MDS**  
Also includes member names listed on the MDSF website.

**$500**  
**Create the Path Towards a Cure**  
In addition, 20% of your membership dues will be dedicated to MDS research.

**Together we are a Community Resource of Hope for those LIVING with MDS.**

Founded in 1994, the MDS Foundation is the only not-for-profit global organization dedicated solely to improving outcomes for patients with MDS.

Over the last 20 years, the treatment and understanding of MDS has evolved in many ways. Once referred to as pre-leukemia, MDS is now recognized worldwide as a blood cancer. Originally, there were no official treatments for MDS. Today, there are 5 approved treatment options with many more in the development phase.

**OUR VISION**

Every MDS patient will benefit from our initiatives and research as early as possible.

**OUR MISSION**

MDS Foundation supports and educates patients, their communities, and healthcare providers, and contributes to innovative research in the fields of MDS and its related continuum of diseases to better diagnose, control and ultimately cure these diseases.
THINKING OF JOINING THE MDS FOUNDATION AS A PROFESSIONAL MEMBER, CHANGE THE FUTURE OF MDS MEMBER OR CREATE THE PATH TOWARDS A CURE MEMBER?

To join the MDS Foundation and help us fulfill our mission of moving closer to a cure for MDS, please visit our website at http://www.mds-foundation.org/professional-annual-membership-application.

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CREATE THE PATH TOWARDS A CURE MEMBERS: David Carden • Chris Holiday • Julia McGuire • Roy Rawlings • Harvey P. Root • Doron Steger • Pamela Nelson • Wei Shao • Janet B. Warfield
UPCOMING PATIENT WEBINARS

WE ARE VIRTUAL!

Given the growing concerns surrounding COVID-19 and for the safety of our attendees, the MDS Foundation will continue to host a series of webinars in place of our in-person patient forums.

Whether you are a newly diagnosed patient, a long-term survivor, or caregiver, our webinar series will have something for you.

We have collaborated with renowned hematology professionals who will address key topics and questions using easy to understand language in a 90-minute format that includes a live Q&A opportunity for all participants.

https://www.mds-foundation.org/upcoming-2021-webinars-for-mds-patients-caregivers

MISSED OUR LIVE WEBINAR?
VIEW PREVIOUS LIVE WEBINARS AT A TIME THAT IS CONVENIENT FOR YOU!

ANNOUNCING THE MDS FOUNDATION’S NEW PROFESSIONAL PODCAST SERIES

MDS PROFESSIONAL REPORT:
THE MDS FOUNDATION IS LAUNCHING A NEW INITIATIVE – MDS PODCASTS!

With the explosion of information in MDS we are continually seeking novel alternative ways to distribute it. Thus, MDSF is venturing into podcasts to fulfill one of our major goals – education. Podcasts have become an easy and popular way to communicate information. This podcast series will provide important up-to-the-minute information on MDS including diagnosis, treatment, and clinical research.

The MDS Professional Report will cover international meetings as well as recently published articles on MDS, combining educational materials with cutting-edge information. The format will include a description of studies by the editors, interviews with experts, conversations, round table discussions as well as other relevant formats. We are planning to include several episodes per year lasting 20-25 minutes covering a range of topics.

SEASON 1: EPISODE 1: TP53 Mutations: Were They Born Equal?
Our host, Professor Moshe Mittelman from Tel-Aviv Sourasky Medical Center, will review four recent studies on TP53 and MDS.

SEASON 1: EPISODE 2: Don’t Withhold Anti-Neoplastic Treatment from your Hematological Patients Infected by COVID
Professor Moshe Mittelman from Tel-Aviv Sourasky Medical Center, will review 4 studies discussing if a COVID diagnosis should impact MDS treatments, therapeutic options for anemia and the use of pevonedistat with azacytidine in high-risk MDS.

We hope you find the MDS Professional Report informative, interesting and useful.
GAMIDA CELL PRESENTS EFFICACY AND SAFETY RESULTS OF PHASE 3 STUDY OF OMIDUBICEL IN PATIENTS WITH HEMATOLOGIC MALIGNANCIES AT THE 2021 TCT MEETINGS OF ASTCT AND CIBMTR

BOSTON, FEBRUARY 9, 2021 — Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases, today announced the results of a Phase 3 clinical study of omidubicel presented in an oral session at the Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy (ASTCT) and Center for International Blood & Marrow Transplant Research (CIBMTR), or the TCT Meetings. Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell transplant solution for patients with hematologic malignancies.

This clinical data set was from the international, multi-center, randomized Phase 3 study of omidubicel that was designed to evaluate the safety and efficacy of omidubicel in patients with high-risk hematologic malignancies undergoing a bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. This is the first presentation of these data in a peer-reviewed conference. The full presentation is available on the Gamida Cell website.

“The results of this global Phase 3 study of omidubicel in patients with hematologic malignancies show that omidubicel resulted in faster hematopoietic recovery, fewer bacterial and viral infections and fewer days in hospital, all of which are meaningful results and represent potentially important advancements in care when considering the patient experience following transplant,” said Mitchell Horwitz, M.D., principal investigator and professor of medicine at the Duke Cancer Institute. “The comparator, a transplant with umbilical cord blood, has been historically shown to result in low incidence of graft versus host disease (GvHD) in relation to other graft sources, and in this study, omidubicel demonstrated a GvHD profile similar to the comparator. Moreover, previous studies have shown that engraftment with omidubicel is durable, with some patients in the Phase 1/2 study receiving their transplant more than 10 years ago. The data presented at this meeting indicate that omidubicel has the potential to be considered a new standard of care for patients who are in need of stem cell transplantation but do not have access to a matched donor.”

Details of Phase 3 Efficacy and Safety Results Shared at the TCT Meetings

Patient demographics including racial and ethnic diversity and baseline characteristics were well-balanced across the two study groups. The study’s intent-to-treat analysis included 125 patients aged 13–65 years with a median age of 41. Diseases included acute lymphoblastic leukemia, acute myelogenous leukemia, myelodysplastic syndrome or lymphoma. Patients were enrolled at more than 30 clinical centers in the United States, Europe, Asia, and Latin America.

Gamida Cell previously reported in May 2020 that the study achieved its primary endpoint, showing that omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment, a measure of how quickly the stem cells a patient receives in a transplant are established and begin to make healthy new cells, and a key milestone in a patient’s recovery from a bone marrow transplant. The median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group (p<0.001).

All three secondary endpoints demonstrated a statistically significant improvement among patients who were randomized to omidubicel in relation to patients randomized to the comparator group (intent-to-treat). Platelet engraftment was significantly accelerated with omidubicel, with 55 percent of patients randomized to omidubicel achieving platelet engraftment at day 42, compared to 35 percent for the comparator (p=0.028). The rate of infection was significantly reduced for patients randomized to omidubicel, with the cumulative incidence of first grade 2 or grade 3 bacterial or invasive fungal infection for patients randomized to omidubicel of 37 percent, compared to 57 percent for the comparator (p=0.027). Hospitalization in the first 100 days after transplant was also reduced in patients randomized to omidubicel, with a median number of days alive and out of hospital for patients randomized to omidubicel of 60.5 days, compared to 48.0 days for the comparator (p=0.005). The details of these data were first reported in December 2020.

Previously unpublished data from the study relating to exploratory endpoints also support the clinical benefit demonstrated by the study’s primary and secondary endpoints. There was no statistically significant difference between the two patient groups related to grade 3/4 acute GvHD (14 percent for omidubicel, 21 percent for the comparator) or all grades chronic GvHD at one year (35 percent for omidubicel, 29 percent for the comparator). Non-relapse mortality was shown to be 11 percent for patients randomized to omidubicel and 24 percent for patients randomized to the comparator (p=0.09).

These clinical data results will form the basis of a Biologics License Application (BLA) that Gamida Cell expects to submit to the U.S. Food and Drug Administration (FDA) in the second half of 2021.

“We believe that omidubicel has the potential to transform the field of hematopoietic bone marrow transplant by expanding access to this potentially curative cell therapy treatment for thousands of patients who are in need of a transplant but lack access to a matched related donor,” said Julian Adams, Ph.D., chief executive officer of Gamida Cell. “Sharing the results of the Phase 3 study of omidubicel with the transplant community is a major moment for Gamida Cell, and we are...”
forever grateful to the patients who participated in this study, their caregivers, and the work of the investigators and their teams.”

**ABOUT OMIDUBICEL**

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with hematologic malignancies (blood cancers). In both Phase 1/2 and Phase 3 clinical studies (NCT01816230, NCT02730299), omidubicel demonstrated rapid and durable time to engraftment and was generally well tolerated. Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03179337). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name Cordin®, which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

Omidubicel is an investigational therapy, and its safety and efficacy have not been established by the FDA or any other health authority.

**ABOUT GAMIDA CELL**

Gamida Cell is an advanced cell therapy company committed to cures for patients with blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn or Twitter at @GamidaCellTx.

**ABFERO PHARMACEUTICALS ANNOUNCES INITIATION OF PHASE 1 STUDY FOR LEAD IRON CHELATOR**

**BOSTON, FEBRUARY 23, 2021** — AbFero Pharmaceuticals, Inc., a privately-held clinical stage pharmaceutical company dedicated to treating diseases of iron overload, today announced the initiation of a Phase 1 study of its lead iron chelator, SP-420, in myelodysplastic (MDS) and myelofibrosis patients (MF) with transfusional iron overload (TIO).

“The opening of this trial in MDS and MF marks another critical step forward on the development path for SP-420,” said AbFero CEO Thomas X. Neenan. “Following the recently awarded Parkinson’s research grants from EUREKA Eurostars and Cure Parkinson’s, this trial is an additional building block in our strategy of developing safe chelators for both hematological indications and diseases of aging where iron is implicated.”

“Transfusional iron overload, from chronic red blood cell transfusion, remains a serious problem for the many patients with chronic leukemia and chronic bone marrow disorders,” explained Dr. Ruben Mesa, executive director of the Mays Cancer Center at The University of Texas Health Science Center San Antonio. “The Mays Cancer Center is grateful for the first opportunity to offer the innovative approach to iron chelation from SP-420 from AbFero to patients with MDS and MF,” he said.

The study, to be conducted by Dr. Elizabeth Bowhay-Carnes, Director of the Adult Non-Malignant Hematology Program at the health science center, also called UT Health San Antonio, will examine the safety of SP-420 in this important population of patients with TIO and will provide the basis for further expansion into longer efficacy studies. The trial is expected to provide key safety data in 2021.

**ABOUT ABFERO**

AbFero Pharmaceuticals, Inc. is a privately-held clinical stage pharmaceutical company dedicated to treating diseases of iron overload. AbFero’s technology is based upon the discoveries of a pioneer in the field of iron chelator medicinal chemistry, Professor Raymond Bergeron, University of Florida. Our therapeutic platform addresses transfusional iron overload (TIO) and iron accumulation associated with diseases of aging such as age-related macular degeneration (AMD) and Parkinson’s disease. AbFero has completed three clinical trials with the company’s lead iron chelator, SP-420.

AbFero Pharmaceuticals, Inc., is based in Boston, Massachusetts, and our subsidiary, AbFero, Ltd., is located in Harwell, UK. For more information, visit: https://www.abferopharmaceuticals.com.

**GERON ANNOUNCES FIFTY PERCENT ENROLLMENT MILESTONE IN IMERGE PHASE 3 CLINICAL TRIAL IN LOWER RISK MDS**

**FOSTER CITY, CA, DECEMBER 10, 2020** — Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced achievement of fifty percent enrollment in the IMerge Phase 3 clinical trial of imetelstat in lower risk myelodysplastic syndromes (MDS). Data from the IMerge Phase 2 were recently presented at the American Society of Hematology Annual Meeting and support the ongoing Phase 3.

“Reaching fifty percent enrollment is a key milestone towards the completion of this registration-enabling Phase 3 clinical trial, and we appreciate all of the support from our investigators and the patients who are participating in this study,” said Aleksandra Rizo, M.D., Ph.D., Geron’s Chief Medical Officer. “We believe that the IMerge Phase 3 will confirm the meaningful and durable transfusion independence and the disease-modifying activity of imetelstat observed from the Phase 2, and that imetelstat could become a much-needed treatment alternative for patients with lower risk MDS.”

The IMerge Phase 3 is a double-blind, randomized, placebo-controlled clinical trial with registration intent. The trial is designed to enroll approximately 170 transfusion dependent patients with Low or Intermediate-1 risk MDS, or lower risk MDS, who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). The primary endpoint is the rate of radiographic response (RR).
Key secondary endpoints include the rate of RBC-TI of at least 24 weeks, or 24-week RBC-TI rate, rate of hemato logic improvement-erythroid (HI-E), defined as a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden, and duration of transfusion independence.

The Company continues to expect full enrollment in the IMerge Phase 3 in the second quarter of 2021. As long as enrollment is completed by the end of the first half of 2021, Geron maintains its projection of top-line results from IMerge to be available in the second half of 2022.

To learn more about IMerge and whether the study is enrolling patients in your area, please visit www.clinicaltrials.gov.

GERON REPORTS TEN IMETELSTAT PRESENTATIONS AT AMERICAN SOCIETY OF HEMATOLOGY ANNUAL MEETING

- Data and analyses highlight the differentiating clinical benefits of imetelstat treatment observed in both the Phase 2 IMerge and IMbark trials
- Additional clinical analyses and data presented on the depletion of abnormal clones and disease mutations strongly suggest that imetelstat has disease-modifying activity
- Biomarker data on reductions in telomerase activity and hTERT expression correlated with clinical outcomes provides evidence of on-target activity of imetelstat
- All ten abstracts submitted were accepted for presentation
- Presentations provide further support of ongoing and upcoming Phase 3 clinical trials of imetelstat

FOSTER CITY, CA, DECEMBER 7, 2020 — Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced that four oral presentations and six poster presentations containing clinical data and analyses related to imetelstat, the Company’s first-in-class telomerase inhibitor, were presented at the 62nd American Society of Hematology (ASH) Annual Meeting. The presentations are available at www.geron.com/r-d/publications.

“Our imetelstat presentations at this year’s ASH provide strong support for our two registration-enabling Phase 3 clinical trials: IMerge, in lower risk MDS and IMpactMF, in refractory MF,” said Aleksandra Rizo, M.D., Ph.D., Geron’s Chief Medical Officer. “We believe the analyses and data from our Phase 2 IMerge and IMbark trials provide strong evidence of imetelstat’s disease-modifying activity, as well as clinical benefits of durable transfusion independence in MDS and improvement in overall survival in MF.”

Lower Risk Myelodysplastic Syndromes (MDS)
ORAL PRESENTATION
Treatment with Imetelstat Provides Durable Transfusion Independence (TI) in Heavily Transfused Non-del(5q) Lower Risk MDS (LR-MDS) Relapsed/Refractory (R/R) to Erythropoiesis Stimulating Agents (ESAs) (Abstract #658)

The oral presentation reported long-term efficacy, safety and biomarker data from 38 patients in the IMerge Phase 2 clinical trial, based on a February 4, 2020 cut-off date and a median follow-up of 24 months. Consistent with prior presentations, 42% of patients achieved >8-week red blood cell transfusion independence (RBC-TI) with a median duration of 20 months, which is the longest so far reported with any agent in relapsed/refractory non-del(5q) lower risk MDS. In addition, 29% of patients were transfusion free more than a year. Reduction in the SF3B1 mutation, one of the key mutations correlated with ineffective erythropoiesis in lower risk MDS, correlated with longer transfusion independence and shorter onset to achieve transfusion independence. These biomarker data together with the durability of transfusion independence provide evidence for the disease-modifying activity of imetelstat. These data were previously presented at the European Hematology Association (EHA) Annual Congress in June.

Relapsed/Refractory Myelofibrosis (MF)
(3) ORAL PRESENTATIONS
Potential Disease-Modifying Activity of Imetelstat Demonstrated By Reduction in Cytogenetically Abnormal Clones and Mutation Burden Leads to Clinical Benefits in Relapsed/Refractory Myelofibrosis Patients (Abstract #346)

This oral presentation reported significant dose-dependent reduction of mutation burden by imetelstat, including complete elimination of mutations in MF driver and non-driver genes. A greater than 20% reduction in variant allele frequency by imetelstat treatment correlated with improved clinical benefits, including higher rates of spleen and symptom responses, bone marrow fibrosis improvement and longer overall survival (OS). As concluded in the presentation, imetelstat demonstrated disease-modifying activity by targeting malignant clones, improvement in bone marrow fibrosis and OS.

Telomerase Activity, Telomere Length and hTERT Expression Correlate with Clinical Outcomes in Higher-Risk Myelofibrosis (MF) Relapsed/Refractory (R/R) to Janus Kinase Inhibitor Treated with Imetelstat (Abstract #347)

This oral presentation reported dose-dependent inhibition of telomerase, as evaluated by reductions in telomerase activity, human reverse transcriptase (hTERT) levels and telomere length in patients treated with imetelstat in the IMbark Phase 2 clinical trial. Analyses of these biomarker data correlated with clinical responses and longer OS. In addition, dose-dependent reduction in variant allele frequency of driver mutations was noted, indicating that imetelstat has disease-modifying activity by targeting the underlying MF malignant clones. As expected for a telomerase inhibitor, treatment with imetelstat at 9.4 mg/kg improved clinical outcomes in patients with shorter telomeres.
and higher hTERT expression at baseline. These data are consistent with telomere biology in cancer cells and provide evidence for on-target mechanism of action of imetelstat through telomerase inhibition. These results were previously reported as a poster presentation at the EHA Annual Congress in June.

Favorable Overall Survival with Imetelstat Treatment Correlates with Other Clinical Benefits in Intermediate-2 or High-Risk Myelofibrosis Relapsed/Refractory to Janus Kinase Inhibitor (Abstract #53)

This oral presentation reported the correlation of overall survival results from the IMbark Phase 2 with clinical benefits observed with imetelstat treatment. The correlation analyses showed a trend of longer OS in patients who achieved symptom response, spleen volume reductions ranging from >10% to >35%, and statistically significant improvement in OS in patients with improved bone marrow fibrosis, in a dose-dependent manner. These results were previously reported as a poster presentation at the EHA Annual Congress in June.

Relapsed/Refractory Myelofibrosis (MF)

(3) POSTER PRESENTATIONS

Collectively, these poster presentations described on-target and disease-modifying activity of the higher dose of imetelstat from the IMbark Phase 2, and how that relates to better clinical outcomes, including OS, fibrosis improvement and symptom response, especially in a subset of patients defined as triple negative MF, known to have poor outcome.

Correlation Analyses of Imetelstat Exposure with Pharmacodynamic Effect, Efficacy and Safety in A Phase 2 Study in Patients with Higher-risk Myelofibrosis Refractory to Janus Kinase Inhibitor Identified an Optimal Dosing Regimen for Phase 3 Study (Abstract #1283)

Imetelstat Treatment Results in Clinical Benefits, Including Improved Overall Survival, in Patients with Higher-Risk Triple Negative Myelofibrosis Relapsed/Refractory to Janus Kinase Inhibitors (JAKi) (Abstract #3084)

Treatment with Imetelstat Improves Myelofibrosis-Related Symptoms and Other Patient-Reported Outcomes in Patients with Relapsed or Refractory Higher-Risk Myelofibrosis (Abstract #3088)

Myeloproliferative Neoplasms (MPN)

POSTER PRESENTATION

Imetelstat Inhibits Telomerase and Prevents Propagation of ADAR1-Activated Myeloproliferative Neoplasm and Leukemia Stem Cells (Abstract #1264)

Collaborators at UC San Diego reported non-clinical data on hTERT and ADAR1 activity in pre-leukemia stem cells and leukemia stem cells (LSC). In various lab experiments and animal models, treatment with imetelstat prevented pre-leukemia stem cells from evolving into LSCs, suggesting telomerase inhibition may be an effective strategy for preventing MPN progression.

Two Trials in Progress – Ongoing IMerge Phase 3 and Upcoming IMpactMF Phase 3

POSTER PRESENTATIONS

IMerge: A Phase 3 Study to Evaluate Imetelstat in Transfusion-Dependent Subjects with IPSS Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) that is Relapsed/Refractory to Erythropoiesis-Stimulating Agent (ESA) Treatment (Abstract #3113)

The IMerge Phase 3 clinical trial is a double-blind, randomized, placebo-controlled clinical trial with registration intent. The trial is designed to enroll approximately 170 transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (MDS), also referred to as lower risk MDS, who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). The IMerge Phase 3 is currently enrolling patients. The primary endpoint is the rate of red blood cell (RBC) transfusion independence (TI) for any consecutive period of eight weeks or longer, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the rate of hematologic improvement—erythroid (HI-E), defined as a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden.

A Randomized Open-Label, Phase 3 Study to Evaluate Imetelstat Versus Best Available Therapy in Patients with Intermediate-2 or High-risk Myelofibrosis (MF) Refractory to Janus Kinase (JAK) Inhibitor (Abstract #2194)

The IMpactMF Phase 3 clinical trial in refractory MF is a registration-enabling trial with OS as the primary endpoint. Approximately 320 patients with Intermediate-2 or High-risk MF will be randomized to receive either imetelstat or best available therapy, which will exclude JAK inhibitors. Key secondary endpoints include symptom response, spleen response, progression free survival, complete response, partial response, clinical improvement, duration of response, safety, pharmacokinetics, and patient reported outcomes.

Geron expects the trial to be open for screening and enrollment in the first quarter of 2021.

ABOUT PHASE 2 IMERGE AND IMBARK TRIALS

The IMerge Phase 2 was an open label, single arm trial to assess the safety and efficacy of a 7.5 mg/kg dose of imetelstat administered as an intravenous infusion every four weeks in transfusion dependent lower risk MDS patients who had relapsed after or were refractory to prior treatment with ESA. The IMerge Phase 2 is no longer enrolling patients, and patients remaining in the treatment phase continue to receive imetelstat treatment, per investigator discretion.

The IMbark Phase 2 was designed to evaluate two dosing regimens of imetelstat

PRESS RELEASES

Ongoing – AND IMBARK TRIALS

Geron expects the trial to be open for screening and enrollment in the first quarter of 2021.
约4.7 mg/kg或9.4 mg/kg（每三周静脉注射一次）在间充质干细胞（MSC）患者中，使用复数效应器抑制剂（JAKi）作为第一线治疗或对JAK抑制剂具有抵抗或耐药的患者。主要的端点包括为靶向B细胞成熟因子（BCMF）的活动提供整体生存（OS）和症状反应率。关键的二级端点包括24周后总症状评分（TSS）、减少至少50%在末梢血象作为评估，以及症状反应率，定义为最大程度的完全缓解率。该试验是完整的并且已经完成。
ART WORKS – VISIONS OF LIFE WITH MDS GALLERY

All of the artworks exhibited here have been created by members of the MDS community, as part of MDS World Awareness Day on October 25th, 2020. They have been created to help the world understand the challenges of living with MDS, while also celebrating personal stories of love, hope and strength.

https://www.mdsartworks.com/gallery/
“Please know that what you are doing is crucial for the whole person. The arts help the patient identity past being lab rat, data point and guinea pig. When my MDS morphed into AML with 40% blasts, I was hospitalized at the University of Washington. I called in the art therapist, music therapist and every supportive care resource person available into my room. The music therapist brought in a keyboard so I could make music and sing. With the art therapist support, I wrote songs about my circumstance so I could explore my emotions. With the help of the art therapist and the art materials she supplied, I made huge wall murals — one, a full body picture of me, another mural of leaves and branches overtaking the wall surrounding the window. I rearranged the furniture in my hospital room, so my bed faced the window. I hung prayer ribbons from the hoist on the ceiling which hung over my bed in case of emergency. The ceiling hoist transformed from a medical device into a go-to place of calm, hope and promise. I made a prayer/meditation station in the room and a writing table to encourage me to get out of bed. Each time a chemo dose was successfully administered, I brought out my rubber chicken (gifted to me from a friend) which was stored in the room underneath the bed pan (renamed “The Coop”) and squeezed the toy to make a sound to signify the sun coming up to the new day and the accomplishment of making it through another chemo injection/drip.”

VALERIE FONS

“Thank you for what you are doing as you remind the world of the essential ingredients for health.”

“Arts are essential for well-being, survival, and life.”

“Art in a hospital room is like a cave drawing — expression and documentation of being alive.”

“As you make your continued invitation for people to participate in your project, please consider that the book is more than a documentation of patients but an invitation for those coming along and after in the medical process to engage their whole person in the journey through the valley of the shadow of death into the light.”
I was originally diagnosed with Chronic Lymphocytic Leukemia (CLL) in 2004 and received Fludarabine + Cyclophosphamide + Rituximab (FCR) treatment, 2nd line, in 2006. What followed was an amazing 14-year remission. In February of 2020, I was diagnosed with MDS and was told that this aggressive bone marrow cancer was the result of the FCR treatment I had back in 2006.

Looking back at how I arrived at this point, I recall how in 2006 I responded to a number of options. Due to a less than stellar prognosis, we sold our business. We also sold our house and moved into a waterfront apartment. The big, life-changing decision I made, however, was getting involved in music. I had owned an old blues harmonica but I really had no idea how to play it. Up until that time, I really had little appreciation of anything related to music. Until my original diagnosis, my whole life had been taken up with family and business, both of which were challenging and amazing.

After my diagnosis, however, I desperately needed something to ease the stress of living with cancer. I had friends who were into music, and over the years, had met a few blues musicians. A few of those artists would invite me periodically, to sit in on their sessions, where I would create some amateurish sounds on my blues harp. Over the next few weeks and months, as I slowly learned the basics, I fell in love with music! Pretty soon, through perseverance, I was able to contribute something meaningful to a performance.

On what would turn out to be another life-changing day, a friend who managed musicians approached me with the idea of recording a CD. I told him he was crazy! I felt that my skill level was not that impressive. However, with his encouragement, I asked myself, “What do I have to lose?” With his generous help, we put together an amazing band of top musicians. We were blessed when Charlie A’Court, an extremely talented singer/guitar player, agreed to be our ‘frontman’. We called our band ‘Little Derek and the Haemo Blues Band’. Our first venue was a live concert, which was recorded and became the first of what would eventually be three CDs.

So there I was with my first ever CD. What was I supposed to do with it? A lightbulb moment happened inside my ‘brain box’ and I requested a meeting with the CEO of the fundraising arm of our hospital here in Halifax. In the weeks ahead, we worked out a way for me to create my own fund through the QE2 Foundation. The money raised would go towards helping haematology patients who were having financial challenges during treatment. From my own experience, I knew full well about the stress of going through treatment and how even small issues could get blown out of proportion. Of course, that just added to the stress. The fund was not created to pay for drugs or treatment but was there to help with day to day financial challenges faced by my fellow patients. It was managed by a social worker in the hematology department, and she was the only person with access to the funds. The decision on how to use the fund and who to help was 100% at her discretion.

For each of our three CDs, I wrote a song. For the first recording, I wrote ‘Haemo Blues’. On the second, I penned ‘Healing Power of Music’ and for the third, ‘You Don’t Understand’. I have attached a link for ‘You Don’t Understand’. I hope you will see that this was the most meaningful recording for me.
Little Derek and the Haemo Blues Band never ‘gigged’, but a couple of times a year we would put on a fundraising concert. Part of that process included recording two more live CDs. I always took pride in advertising that 100% of ticket sales for the concerts and 100% of CD sales went straight into The Little Derek Leukemia Fund. That meant that all costs incurred in staging the concerts, as well as recording and manufacturing the CDs needed to be covered. I managed that through sponsorships and donations. A lot of my time and energy went into making those events happen. Over 6 years, my band and I contributed $200,000 to the needs of patients, to try and assist in their time of crisis. To me, the effort I put into that project was more than worth it. In the year I turned 75 years old, the group disbanded, and I decided to put all my energy into my family.

Although we no longer performed as a band, that did not mean I did not play regularly. Whenever I got a chance, I would sit in for a set with my musician friends. My music took me to Cuba where, for many years, I would perform at a resort. That new phase of my life started while on vacation there. The experience led me to become an agent and taking musicians from Nova Scotia there to play. Of course, I always played on stage with them. It was during that period when I first got the courage to sing before an audience and have been doing so ever since.

Over the past 16 years, my life has been amazing! I believe that my new attitude, combined with a healthy lifestyle made the original CLL diagnosis of six years continue on for many more years. Finding that ‘something’ to take my mind off my health challenges, was invaluable in my previous remission. Music was the best medicine ever!

I have included links to two of my songs. I hope you enjoy them and they inspire you.

https://youtu.be/PVe2_QSBJmw
“You Don’t Understand”
https://youtu.be/3vxRksB39gE
“Haemo Blues”

Now I face a new challenge... MDS is much tougher than my CLL. With COVID and my compromised immune system, it is difficult to get out and play. I will need to find other ways to keep my mind and body active.

I will leave you with this. My absolute belief in myself (which I have always had) and the fact that I am my number one advocate in all matters of life, especially my health challenges, helps me immensely in facing the challenging scenario of MDS.
At the age of 49, Bergit fell ill with the still incurable malignant blood disease, myelodysplastic syndromes (MDS). She had to take early retirement in 2011 because of this disease. In 2007, Bergit started to contact other patients and patient organisations via the Internet. Over the years, her growing number of contacts, her German, European and international networking, as well as her attendance at patient events and specialist congresses, have increased her desire and opportunities to become more professionally involved in patient representation. Today, Bergit is on the Board of Directors of the LHRM, a patient organisation for leukaemic patients and their carers (the German Leukämiehilfe Rhein-Main e.V.), and is the contact person of the German MDS-PAT-IG (www.mds-patienten-ig.org).

https://www.mds-foundation.org/out-of-shape-a-patient-story

The German translated version can be ordered from LHRM-MDS Patienten-Interessen Gemeinschaft by emailing buero@LHRM.de.

Received the book. It was inspirational and encouraging to never lose hope no matter how hard the sufferings of an MDS patient. Thank you so much for this book!

Agnes L.

I just received the copies of Out of Shape that you so generously provided. Thank you so very much! This has changed our lives so dramatically and with your help, we should be able to face each day with more knowledge and confidence.

Dixie L.

Thank you so much for the book. I can’t put it down – it is as if it is our story. You are so right on with everything. I’m in awe of your details, analogies, and honesty. Thank you so much your book is a gift I will be sharing with our entire family, so they better understand what dad is going through. Many thanks for your great book!

Connie M.
MDS IN THE TIME OF COVID-19

ANNA STEEGMANN
New York, New York

PREFACE
In 2011, my husband of 25 years died shortly after surgery for a brain tumor. In the years after his death, I experienced waves of intense grief over this deep loss. Over the next four years, I lost my mother, my youngest brother and two lifelong friends, one to suicide.

Eventually I found joy in living again. I was teaching two writing classes per semester at The City College of New York and loved working with students from the most diverse backgrounds in the country. I did not intend to retire anytime soon. As a staff writer for the New York City Jazz Record, I attended concerts, interviewed musicians and reviewed new releases. I had joined a writers’ collective named “Writers with Attitude”: I was one of only two white members, and at 65, the eldest, in the group. After years of mourning, New York felt once again like an exciting city to me: I went to museums, gallery openings, concerts, and plays. I had great friends. To start off the new decade the right way, I treated myself to a week in Jamaica in February of 2020.

THE WHOOSHING
Around that time, I noticed a whooshing sound in my ears. During the day, I could distract myself but at night, I could not sleep without the fan going to drown out the mysterious sound. A hearing test found nothing wrong with my ears. Yearly stress tests had shown that I was in excellent physical shape despite my mitral valve prolapse and a family history of coronary arterial disease. Typically, I could keep up with people half my age at the YMCA’s spinning classes, now I barely slept because my roommate blasted her TV without interruption. The whooshing continued. I decided to see my cardiologist, who thought the whooshing might be related to my heart and ordered a spectral Doppler analysis — it revealed no abnormalities, and neither did the trans-thoracic echocardiogram. A blood test showed that I was anemic. She wanted to take more blood for more tests. I saw her on Thursday, March 5th, and I was scheduled to call her on Monday for the results. But she called the next day, reaching me at my accountant’s office: “Drop whatever you’re doing, get into a cab immediately and meet me at my office.”

A SINKING FEELING
I took the subway. On the platform, a man was playing Eric Clapton’s “Tears in Heaven” on his steel drum. I was 65; my husband died when he was 65. The song seemed like an omen that my time, too, was very limited. Would I be reunited with my husband soon?

My cardiologist explained that I was deficient in all three cellular components of my blood: the red and white cells as well as the platelets. This was called pancytopenia. She then called an oncologist and a hematologist and read them the results of my blood test. I sat next to her, as they communicated about me in an incomprehensible language. Her colleagues recommended that I go to the emergency room right away. The blood work indicated that I might have leukemia.

FOUR DAYS IN THE HOSPITAL
I had not been hospitalized since my appendectomy when I was ten. On the TV in the emergency room at Lenox Hill Hospital, the anchor reported forty-four coronavirus cases in New York State. New York City residents were rapidly emptying the supermarket shelves. The man in the bed next to me could not stop coughing — was he more dangerous to me than my blood?

During my four nights at Lenox Hill, I barely slept because my roommate blasted her TV without interruption. The whooshing continued. I tested negative for hepatitis C, HIV, and herpes. My cardiologist visited me every day. All the nurses and doctors were wearing masks. I once fainted on the floor of the bathroom. On my last day, I underwent a bone marrow biopsy. When I left the hospital, I had to hold on to my friend Claudia who had picked me up. At home, I experienced severe diarrhea. Once I even had an accident in the elevator. The whooshing continued.

THE DIAGNOSIS
My cardiologist called me with good news: “You don’t have lymphoma or leukemia.” On Friday the 13th, I was going to get the results of my bone marrow biopsy. I wasn’t worried.

“Your final diagnosis is myelodysplastic syndrome,” the hematologist said. “You have a bone marrow production problem. Your white, red blood cells and your platelets under-produce.” She then handed me a Xeroxed paper with more information about the disease. I was in shock. My knowledge about bone marrow was limited to Markklößchensuppe, a delicious soup made with beef bone marrow dumplings. My mother made it throughout my childhood and youth in Germany.

“Some people with MDS are treated with medication and blood transfusions,” she said, “but your only hope for a cure is to have a bone marrow transplant. Only 30–35% of all patients make it.”

I was told to call the bone marrow transplant center at Mount Sinai immediately:
"You’re in the high risk category," she said calmly. “You’re already 65 and they don’t usually do bone marrow transplants for people over 65. “

I was stunned by this turn of events and the hematologist’s lack of empathy.

“I will be on vacation for three weeks. Make an appointment with my receptionist for the beginning of April. If you’re feeling bad this weekend, get yourself to an emergency room and ask for a blood transfusion.”

That, for a few weeks, was the last thing she said.

TRYING TO FIND THE BEST POSSIBLE CARE

As Covid-19 was raging cross the city, I did not go to an emergency room and ask for a blood transfusion. At home, I read up on MDS online. I learned that it was a rare cancer, frequently caused by exposure to toxic industrial chemicals such as lead, benzene, pesticides, heavy metals as well as tobacco. I had been a heavy smoker for 20 years. I grew up in Europe’s largest industrial region. Our air and rivers were polluted from the mines and steel factories. On my way to school on my bike, I always rode past the chemical plant. One summer there was an accident in the plant and the entire town was covered with a white substance that looked like snow. Everyone was coughing, covering his or her mouths with a scarf. Did this cause my MDS?

When I saw the doctor in person on April 13th after a TeleMed visit the week before, she was wearing a mask and a face shield. Ever more remote behind her armor, she announced infusions of Vidaza the following day for five days each month without mentioning the word chemotherapy. Injections with Neulasta were to follow. She sent me off with two Xeroxed papers explaining the purpose and side effects of both.

New York City meanwhile had become the epicenter of the pandemic. Governor Cuomo declared a state of emergency on March 7th. My college switched to online instruction. On March 20, Mayor De Blasio issued stay-at-home orders and established curfews. Hospitals and nursing homes experienced a shortage of protective gear and ventilators. I used my time to learn how to teach online and to learn more about MDS, including the stages of dying from MDS. The MDS site of the Berlin hospital Charité listed a whooshing sound in the ears as one of the symptoms of MDS, an indication of anemia. At last, I had found an explanation for that torment — on my own.

I contacted hospitals and doctors that the MDS Foundation deemed Centers of Excellence. No one answered my phone calls and emails. No one admitted new patients. The whooshing continued.

My friend Elizabeth had been successfully treated for lymphoma and breast cancer at Memorial Sloan-Kettering Cancer Center. She called, emailed and possibly harassed the head of the leukemia department and her assistant. She pleaded my case until the oncologist gave in. She was not allowed to take me on as a patient now but she would consult with my hematologist. Ultimately, I might be able to transfer to Memorial Sloan-Kettering.

Shortly after, I received a call from the bone marrow transplant center of Memorial Sloan-Kettering. All transplants were on hold. The hospital had to keep their beds free for Covid-19 patients. But they were going to send me an HLA kit (human leukocyte antigen test to determine tissue compatibility for organ transplantation) to begin the donor search. I was warned how difficult and dangerous the procedure was, and how low the success rate. I would have to be in the hospital for at least a month and afterward I would have to live with a caretaker for six months, possibly longer.

CHEMO

The first two rounds of chemotherapy followed by the Neulasta shots were brutal. The Neulasta caused the most aching bone pain imaginable. I asked my friend to go to the pharmacy for me to get me Tylenol. Rite Aid and CVS were all out of Tylenol. People had been stocking up on over-the-counter medicines. Luckily a friend who lived in the neighborhood had a bottle at home and shared some pills with me.

One day, I collapsed in the street as I was walking my dog. Sitting on the stairs of an apartment building, an older man looked at me and asked, “Dialysis?” “Chem,” I answered. He sat down next to me until I felt stronger and then walked me home. “I live in apartment 4D,” he said. “Ring my bell anytime you’re feeling bad.” My friends and neighbors came to my rescue by walking my dog, bringing me food, and driving me to the clinic.

EXPLORATION

My diagnosis was MDS –EB 2, which stood for excess blasts. I was given a life expectancy of one to three years. My friend Drunell connected me to a cancer doctor in Boston. “Most important for you is to click with your oncologist,” he said. “Memorial Sloan-Kettering is an excellent place but it’s a busy factory. You might never get 30 minutes with your doctor.”

I tried to find out everything I could about MDS from a patient’s perspective. I read Robin Roberts Every Body’s Got Something; I joined the MDS Facebook group and spoke to people on the phone who had undergone bone marrow transplants. Linda from San Francisco said, “You can write off one year of your life but after that you’ll be fine.” Julie had been treated at Memorial Sloan-Kettering. Her transplant failed and she developed Multiple Myeloma; she was hoping for a second transplant. It was scary to learn about all that could go wrong.

THE HEIGHT OF THE PANDEMIC

During full lockdown in March and April, an eerie silence took hold of New York City, interrupted by boisterous birdsong at a previously unheard volume as well as the constant wailing of ambulance sirens. There were hardly any cars on the street and almost no planes in the sky. Every night at 7:00 p.m. cars would start honking; people in the street would stop and applaud, whistle and yell; those at home would open their windows and bang on pots and pans — to thank the heroic
health care workers. The parents of two of my students died. When their parents lost their jobs, many of my students had to help put food on the table and pay the rent. Often, they took on dangerous work in food delivery. I worried about them. April saw a record high of newly diagnosed cases and 29,000 more deaths than during the same month a year before.

TURN-AROUND

By May, less people were dying from Covid-19. In June, I started daily Vidaza injections at Memorial Sloan-Kettering, without the dreaded Neulasta that had caused me so much pain. My cancer turned into a fulltime job. Often, I was in the clinic for five hours — waiting for labs, then waiting for the results of the labs, while reading the New York Times and listening to my Lift Me Up playlist. When the blood finally arrived, I would always look at the names of the places on the bags and say quietly, “Thank you, donor from Rockford, Illinois.” The transfusions diminished the whooshing and elevated my energy level tremendously, but they could not prevent bruising, a symptom of my low platelet levels. My stomach was so black and blue from all the injections that the nurses could barely find a spot for the needle. At least my mouth sores disappeared when I gargled with a combination of baking soda, salt and water.

The head of the leukemia department became my oncologist. Even if we were on the same hospital floor, I would only ever see her via TeleMed. Terrible acoustics and frequent tech problems sometimes forced us to speak on the phone instead. We didn’t establish a personal relationship, but I felt that I was in good hands.

Memorial Sloan-Kettering Cancer Center was indeed a factory, albeit a luxurious one. Walking into the building at 530 E. 74th St, I felt I was entering the Hilton Hotel. In the waiting area, patients had a view of the East River, Roosevelt Island and Queens. The walls were covered with expensive art works. Patients had their own treatment rooms with reclining chairs and TVs. They could help themselves to cappuccino and order food from the cafeteria. At the previous clinic, I sat with all the chemo patients in one tight room — I never felt safe. But no matter your diagnosis, or the severity of your illness, in both clinics you could only enter alone.

Some members of my MDS Facebook group had become experts on their disease; I did not read all my lab or bone marrow biopsy reports — it was just too labor-intensive to Google all the terms. “Just tell me what I need to know,” I told the nurse practitioner. Daily meditation helped keep my anxiety at bay. An agnostic since age 10, I nevertheless was grateful that my pen pal in jail as well as my super, my neighbors and friends were praying for me.

After six months of chemo, my cancer was in remission. My BMT was scheduled for October. My oncologist and her assistant said good-bye to me via TeleMed.

“So I won’t see you again?” I asked.
“Not unless your cancer comes back.”
“In that case, thank you for all you did for me. You’re both very nice women but I’d rather not have to see you again,” I said.

The following week, I had a TeleMed visit with the transplant doctor. A suitable donor had been found, and on October 16, I would be admitted to the hospital. I would have to undergo many exams before admission, see the dentist, gynecologist, have an echocardiogram, a mammogram, an EKG, an endoscopy and a colonoscopy, a pulmonary function test and, last but not least, another bone marrow biopsy.

FRUSTRATION EXPLODES

Following the death of George Floyd, protests erupted all over the city. There were daily rallies, vigils, demonstrations. I watched the protests on 125th Street from my living room window for twelve consecutive days. MDS and the pandemic limited me to the spectator role: I could not risk being around hundreds of people.

The angry illegal fireworks started in the first half of June and lasted for weeks — not pops of firecrackers but real explosives, starting in the afternoon and continuing throughout the night, often until 5:00 a.m. The thunderous booms made me feel as if I was living in a war zone. No one could sleep. Dogs went crazy. The police were slow to react.

SETBACK

My ideal donor could not get an appointment to have his bone marrow harvested: all appointments had been delayed because of Covid-19. The following month, my ideal donor was no longer available. A second candidate backed out. But the third, a 34-year-old woman living in a foreign country, was still available. My hospital admission was moved to November. I would have to undergo another round of chemo.

OUR PATIENT STORIES

The day of my bone marrow transplant
My doctor advised me to give up teaching. This was the hardest decision I had to make.

**CARPE DIEM**

At the beginning of summer, many pandemic restrictions were lifted in New York: the mood rose, irrepressibly. I visited the Botanical Garden, attended a press opening at the Guggenheim museum, met friends at outdoor restaurants, and spent many hours in Central Park. My Access-A-Ride driver, a much younger man from Georgia, the former Soviet Union, named Vakho, pursued and distracted me. My cancer did not deter him. “You’ll be fine, I know it,” he said with conviction. We sent sexy text messages and made plans to meet. Soon the temperature rose to 98 degrees, and without any air-conditioned spaces for a rendezvous, our budding romance wilted.

**HOPE FOR A NEW BEGINNING**

On November 7, a radiant autumn day, I was waiting outside the vet’s office for my dog — in this ninth month of the pandemic, owners were still not allowed to accompany their pets inside. Suddenly the young woman with the adorable pug shouted, “Biden won! Biden won!” People on the sidewalk started screaming, dancing, and singing: “Hit the road, Don, and never come back, no more, no more...” Others poured out of their buildings with banners and musical instruments; drivers madly honked their horns — all of Malcolm X. Blvd. erupted in wild noise, full of joy and hope. “Biden won!” Others poured out of their buildings with banners and musical instruments; drivers madly honked their horns — all of Malcolm X. Blvd. erupted in wild noise, full of joy and hope

The next day I started intense chemotherapy and I had never been separated for so long.

**TRANSPLANT AND BEYOND**

On Friday, November 13th, I entered the hospital. After the catheter was placed, I went to my room, unpacked my suitcase, put up photos of friends and family and the places I intended to visit again — Berlin, Vienna, Venice, the Baltic Sea and Morocco. I arranged my collection of lucky charms on my nightstand, my mother’s rosary among them. The next day I started intense chemotherapy with Flurabine for a week, followed by a day of rest, and then the transplant. My donor’s stem cells entered my bloodstream through my catheter — it was pain-free and lasted about an hour. But the following two weeks were pure misery with frequent diarrhea and vomiting, often at the same time. On some days, I had to change my underwear five times.

Food was repulsive; all I could tolerate were small portions of mashed potatoes with gravy. I have never felt so crummy in my entire life. But in spite of my wiped-out immune system I was allowed one visitor per day. These visits made me feel loved and supported. One condition for leaving the hospital was that I could walk by myself. Whenever diarrhea didn’t keep me close to the bathroom, I made my rounds through the hallways, rolling along my IV pole.

Before being admitted to the hospital I had been rather ambitious: I was going to get a lot of reading done, brush up on my French, write long letters to friends. None of that happened. I managed to write brief group emails to my friends and to send text messages to my MDS pen pal Kirk who was undergoing his second transplant at a hospital in Ohio. Compared to him, I felt fortunate: he was not allowed any visitors; not even his wife was permitted to enter the hospital.

“Take it one day at a time,” I was told, but an entire day of misery was too much to face. So I divided the day into three-hour segments. At 9:00 a.m., I said to myself, I have to make it to noon. At noon, I said, I have to make it to 3:00 p.m. My strategy helped a lot.

On December 16, I was released. A nurse put me into a wheelchair. On the way to the elevator a cheering group of nurses and doctors were lined up on both sides, like an honor guard. Coumba, my favorite nurse’s aid from Senegal, handed me a golden pair of scissors to cut a green ribbon. Then she placed the ribbon around my neck. Everybody applauded.

**THE FIRST 100 DAYS**

Marla was waiting for me at home. I had lost 15 pounds in the hospital and now weighed just 111 pounds. I felt weak and shaky but in good spirits. I was thrilled to be back home and to be reunited with Oskar.

The lucky charms I placed on my nightstand.
Not all doctors would allow their patients to live with their dog so soon after a transplant. I was grateful that my doctor recognized the emotional benefits of having my dog with me over the medical risks. He was not allowed to sleep in my bed or lick my face, and I could not pick up his poop — Marla came to the rescue. She also made delicious chicken soup for me every day.

For six weeks, I had to return several times each week to MSK’s Red Team, the post-transplant care unit. I was severely deficient in magnesium and needed frequent transfusions of blood, platelets and magnesium, administered painlessly through my catheter. I had to take an enormous amount of pills every day — some were for my GVHD, others were experimental drugs to prevent the rejection of my donor’s stem cells.

My doctor was pleased with my progress. “You’re doing better than expected,” she kept saying. Twice I had severe diarrhea, once I collapsed on the kitchen floor. My appetite, helped by steroids, came back. Every day I felt a little stronger; every day I could walk a little longer. I was proud of myself when I made the hour and a half walk to Central Park and back.

Walking — sometimes with a friend — was my only diversion from spending all my time at home or MSKCC. After six weeks I was released from the Red Team to the regular clinic — a huge step forward. As Day 100 approached, my doctor told me that I could live alone again and even go shopping during off hours — another big step.

On Day 126 after the transplant, my doctor expressed concerns about the results of my latest BMB and my GVHD. She took me off the medications that suppress my immune system. She also told me that I might have to go back to chemo, this time not seven days a week, only five. I’m trying to stay calm. My neighbors and friends, my super and pen pal in jail will have to pray for me, the non-believer, once again. As always, their prayers are very much appreciated.
THE DAY MY LIFE CHANGED

FIONA MCWHIRTER
Queensland, Australia

My name is Fiona, I am 48 and live in regional Queensland Australia. My hometown is 650 km away from our capital city.

My story starts with irregular blood tests over many years indicating thrombocytopenia, leukopenia and neutropenia. Particularly prominent during my pregnancies.

In 2019, my current GP did a series of bloods; it was after it was confirmed there were no other abnormalities found in any of the screenings that I was referred to the Haematology Department. The wait between the referral in November 2019 and the appointment in Feb 2020 was excruciating. I told no one my fears. I am a nurse, so I had ALL of the potential scenarios going through my head.

At my appointment it was suggested I have a bone marrow biopsy to rule out any underlying issues. The specialist was not concerned as I was asymptomatic aside from fatigue. I had been putting the fatigue down to being a mum to 5 busy boys (let’s face it that’s A LOT of food!) and living a 35 minute drive from town.

During the lead up to my bone marrow biopsy, I recalled all the BMB I had seen or attended to and became quite unsettled. Again, I told no one my fears or anxieties. I had local anaesthetic to the site of the procedure and away we went.

Now as a nurse I need to know everything about everything. My poor haematologist was grilled with so many questions and thankfully the BMB was not as bad as I had anticipated.

Then another wait. For results. The anticipatory anxiety got a bit overwhelming at times. Again, I didn’t share my feelings with anyone so as not to cause concern in case the results were not clear.

The results took longer than expected as the pandemic we know as COVID 19 hit the world and our laboratories were overwhelmed with their workload.

Also turns out the results were not clear. COVID meant the cancer care clinics were doing mostly phone consultations. SO in May 2020 I was given the diagnosis of Myelodysplasia Syndrome over the phone. Cytogenetics were not yet available so more waiting.

The haematologist told me not to google it and to only read the information he would provide until we had the big picture. For once I did as I was told.

The big picture was MDS-MLD low risk. In all my years of nursing I had never heard of MDS. So I began researching and joining groups for information and support. The amount of different information can be very overwhelming and at times when you read that someone has died it still is overwhelming.

How do you tell your family you have cancer? Five children aged from 22 to 10. We felt it required a systematic approach of age appropriate information. The younger boys were very upset. To them the word cancer equates to death. We reinforced living with cancer is very different to dying from it.

We also involved an organisation known as CanTeen who provide support for young people with family members with cancer or themselves living with cancer. They have been amazing. It helps the kids feel less alone and isolated.

My husband attends the appointments with me which I appreciate so very much. I try not to share my negative feelings very much as I don’t want to be a burden. I understand how difficult it is to ride the roller coaster of MDS so putting extra worries onto him is not something I choose to do.

In October 2020, I participated in the event “Light the Night” which raises money for the Leukemia Foundation in Australia. This organisation has given me my own support person to answer questions, get resources from and support through the confusion and overwhelming feelings. It also provides accommodation, transport and other assistance to families having to travel distances for treatment. A resource I am so grateful for.

Later the same month, my family and friends participated in the MDS Foundation Global Walk. I did television, radio and newspaper interviews to raise awareness about MDS. We were the only team registered in Australia. My hope is to build community awareness that having a rare disease can be so isolating when so many do not have a level of awareness or understanding.

MY HOPE IS TO BUILD COMMUNITY AWARENESS THAT HAVING A RARE DISEASE CAN BE SO ISOLATING WHEN SO MANY DO NOT HAVE A LEVEL OF AWARENESS OR UNDERSTANDING.
I went to Brisbane for a second opinion and had another BMB and other tests. The findings were similar except for identifying the KRAS mutation. No one is clear on how that affects my prognosis or treatment as there has not been enough clinical studies done. (I only discovered this information in March 2021.)

To date, I am lucky. My platelets, WBC and neutrophils remain quite low but not low enough to require transfusions, nor have I needed to commence treatment. I am currently known as ‘wait and watch’.

I hate the stress this disease causes my family with its uncertainty, unpredictability and symptoms no one can see or understand. I do not show the depth of my worries and fears to my family. I do get frightened and I do get anxious about the future and my family’s future. But mostly the diagnosis has taught me meditation, yoga, mindfulness and being in the moment is the best gift I can give myself and my family. Nothing else is guaranteed.

In May I am participating in the ‘World’s Greatest Shave’ to raise funds for the Leukemia Foundation. I am shaving my head as is my husband. Our 5 kids are colouring their hair to raise money for CanTeen.

I try to live life as loudly and with purpose as much as my aches and fatigue allows. I have reduced my work hours as my job is stressful, and both the Haematologist and GP had indication that for my ongoing health I needed to reduce stress levels.

Thank you for taking the time to read my story to date. To all of those with MDS I see you, you are not alone, and I thank you all for sharing your stories and information on the groups I have joined. For those supporting and caring for those with MDS, THANK YOU for all you do. Nobody understands the roller coaster that is MDS as much as us and I know I appreciate the support more than the provider will ever know.
In March of 2017, my dad was diagnosed with MDS (RARS) that was discovered after a routine colonoscopy incident that led to a bleeding episode requiring a three-day hospital stay, a couple of transfusions, and then a “watch and wait” period until we finally got the answer we needed from a local oncologist.

My initial feelings were absolute shock and devastation that my lifetime hero and best friend had an incurable rare disease, and there was nothing I could do about it. That’s where I was wrong... there was a lot I could do, and it was just a matter of “changing gears” from negative to positive. After almost a year of trying to find answers as to what was wrong with him, and why he wasn’t bouncing back from the colonoscopy issue that was the catalyst for his severe anemia and iron binding issues, it became very clear that my new mission in life would become advocacy. I am a big believer that you have to be your own best advocate not only in matters of health, but life in general. My dad is a very trusting person and just followed the guidance and direction of his long time, trusted primary care physician. I knew that something bigger was going on and it was just a matter of being persistent and asking the right questions of the right people. Questioning physicians and their decisions is like walking on a thin sheet of ice, but luckily I had the right treading.

This experience gave me the opportunity to use my medical background and passion to dig into the science aspect of this rare disease and use my human relation skills to make the journey as tolerable as possible for my dad, mom, self, and family. Everyone wants to trust their doctors and medical team professionals and hope for answers and solutions. Through this experience it became crystal clear that if you don’t fall into the exact right hands or have a black and white issue, you are really on your own to change the course of the rest of your life.

Having a 20+ year background in medical IT, I was able to understand the magnitude of this diagnosis and navigate through all the resources available to learn as much as we could and make the best decisions. My dad is pretty good with using his computer, but being 83 at the time of his diagnosis, finding information and resources was easier for me to get quickly and I would send everything relevant I could find for him to read and absorb.

It gave us an opportunity for an even deeper bonding experience, though the subject matter was/is grim. My dad and I are from the same mold, and fortunately our DNA helped us stay positive as we journeyed into the unknown. It gave us many more opportunities to spend time together and certainly different things to talk about and learn together.

My new role as daughter advocate included going to every doctor visit together and making sure his care team knew he had a strong support network. I believe this was critical during all of his transfusions, bone marrow biopsies and follow up visits. There is safety in numbers and very often two heads are better than one. There were times when roadblocks were present, and being the bulldozer that I am at times, we were able to plow ourselves through to reach the best solutions for the issues we were struggling with. The one big obstacle I can’t change right now is how the pandemic has changed everything. I’m no longer able to be in the infusion room with him during his
transfusions (which were great opportunities to have a few hours of one-on-one time), though I have been granted special clearance to be present during doctor visits/procedures. Thankfully, this past summer my dad was able to get on Luspatercept therapy shortly after it received its FDA approval... that has helped reduce the frequency of his transfusions and almost cut them in half of what he was doing prior. We do miss many of the things we used to do together and with family, and our “fun” trips are pretty much all but gone, but we do the best we can to make the most of each day.

We are big believers in teamwork, collaboration, and partnerships, and because of that, we have met some amazing people along the way that have made this miserable diagnosis easier to cope with. Very often when you encounter any serious health issue, being or feeling alone is sometimes the worst part of it. We are grateful for the wonderful people out there that care about helping others and have been so helpful in providing resources and activities to make the best of this awful disease and all that comes with it. Another wonderful part of the journey is that I have found some unique volunteer opportunities that involve helping raise awareness for MDS and the rare diseases.

As a caregiver and advocate I know how hard it is to be in that role, especially for someone you love so much. I also know that having people you can trust and rely on is critical in keeping your spirits up. When I have my dark days, and there have been many, I try and find something I can do to help someone else instead of feeling sorry for myself — that in itself has been life changing for me as I cope with this disease, and what the future holds for my hero. It also helps when my dad tells me that he couldn’t imagine a better caregiver and advocate than me, and I am truly honored to be able to be by his side through it all.

I don’t know what the future holds or how much time/quality of life my dad has left, but I know that the “power of together” makes the world a better place and I am grateful for every day that we have. I am also grateful for the wonderful people we’ve met along the way because of this disease, and all of YOU that have shared “their story” and inspired me to share ours.
YOU AND AML: AN ANIMATED PATIENT’S GUIDE TO ACUTE MYELOID LEUKEMIA

This resource is intended for patients with acute myeloid leukemia (AML). You will find expert advice about AML, AML with myelodysplasia-related changes (AML-MRC) and treatment-related AML (tAML) to help you discuss key issues with your healthcare provider and make important decisions related to management and treatment.

“YOU AND AML” CONTAINS 4 LEARNING MODULES:

- Understanding AML
- Understanding AML-MRC and tAML

Each module contains easy-to-understand animations with audio narration, video explanations by AML experts, patient interviews, and illustrated slide shows.

BUILDING BLOCKS OF HOPE

*You or someone you know has been diagnosed with AML.*

Hearing the words Acute Myeloid Leukemia or AML can be frightening. The diagnosis of AML is often unexpected and filled with both immediate and long-term challenges. You probably have many questions. Allow yourself time to adjust to the diagnosis of AML. Take time to explore the Building Blocks of Hope®, it is designed to help get you the information that you are looking for and take an active part in your AML journey. This is a great way to share this information with family and friends. The AML BBoH contains four chapters and a glossary of terms:

Chapter 1: Understanding Acute Myeloid Leukemia
Chapter 2: Seeking Treatment
Chapter 3: General Resources for Living with AML
Chapter 4: The MDS Foundation
Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the U.S. Food and Drug Administration (FDA) approved a revised label for Vyxeos® (daunorubicin and cytarabine) to include a new indication to treat newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in pediatric patients aged one year and older. The approval of Vyxeos for this indication is supported by safety data from two single-arm trials: AAML1421, conducted by the Children's Oncology Group (COG) and CPX-MA-1201, conducted by Cincinnati Children's Hospital (CCH) and evidence of effectiveness from an adequate and well-controlled study in adults.

“At Jazz Pharmaceuticals, we believe all patients living with complex conditions deserve solutions, and work diligently to expand the science behind our therapies to ensure the greatest number of patients can benefit from our medicines,” said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development and chief medical officer of Jazz Pharmaceuticals. “While pediatric patients represent a relatively small percentage of total AML patients, there is a critical need for more effective therapies in this setting. The expansion of the Vyxeos label to include children is a welcome and necessary advancement in support of some of our most vulnerable patients,” said Dr. Edward Anders Kolb, M.D., director of the Center for Cancer and Blood Disorders at Nemours/Alfred I. DuPont Hospital for Children and chair of myeloid disease committee at COG. “Jazz has been a wonderful partner in pediatric drug development and we are grateful for the continued work being done to provide safe and effective therapies for children.”

About Vyxeos® (daunorubicin and cytarabine)

Vyxeos is a liposomal combination of daunorubicin, an anthracyline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor, that is indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older. For more information about Vyxeos in the United States, please visit https://vyxeos.com.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical company dedicated to developing life-changing medicines for people with serious diseases — often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep medicine and movement disorders, and in oncology, including hematologic malignancies and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in more than 90 countries. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.
Find the Right Fit is a program from Jazz Pharmaceuticals, developed with consultation from the Myelodysplastic Syndromes Foundation, Inc. and the Cancer Support Community.

References
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We are offering an opportunity to memorialize your loved one (at no cost) on the MDS Foundation website.

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www.mds-foundation.org/memory-wall
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Do you or someone you know have newly diagnosed Higher-Risk Myelodysplastic Syndrome (MDS)?

Consider enrolling in the VERONA study—a clinical research study evaluating venetoclax in combination with azacitidine, versus azacitidine alone. The study is evaluating the effect of these treatments on Higher-Risk Myelodysplastic Syndrome (MDS).

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- Are ineligible for a stem cell transplant OR are eligible for a stem cell transplant, but have not yet identified a donor or arranged for the transplant

If you meet these criteria and are interested in participating, please contact your doctor to discuss the VERONA study and your eligibility.

For more information, visit ClinicalTrials.gov and search NCT04401748.

Venetoclax is an investigational drug that is not approved by the FDA or other global health authorities in MDS. Safety and efficacy have not been established in MDS.
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