Geron Announces Publication of IMerge Phase 2 Data in Journal of Clinical Oncology

Results support ongoing IMerge Phase 3 clinical trial

FOSTER CITY, Calif., October 28, 2020 -- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced that data from the IMerge Phase 2 trial were published in the Journal of Clinical Oncology. The article entitled, “Imetelstat Achieves Meaningful and Durable Transfusion Independence in High-Transfusion Burden Patients with Lower Risk Myelodysplastic Syndromes Patients in a Phase 2 Study,” is available online. The publication includes data from all 57 patients enrolled in the trial as well as data for the 38-patient target patient population previously reported at the European Hematology Association Annual Congress in June 2020.

“With a median duration of 21 months, the durability of transfusion independence observed with imetelstat in the IMerge Phase 2 trial is a clinically meaningful outcome for patients,” said David Steensma, M.D., Edward P. Evans Chair in Myelodysplastic Syndromes Research at the Dana-Farber Cancer Institute and Associate Professor of Medicine at Harvard Medical School, and lead author of the article. “In addition, the reduction in malignant clone size during imetelstat treatment suggests potential disease-modifying activity, which also could be meaningful from a clinical perspective. The adverse event pattern observed in this trial was similar to previous studies of this drug.”

The publication reports efficacy, safety and biomarker results from the IMerge Phase 2 clinical trial. As stated in the paper, imetelstat treatment produced meaningful and durable transfusion independence (TI). TI was consistently observed across different patient subgroups, including ring sideroblast positive (RS+) and RS-, as well as high and very high transfusion burdened patients. The data also suggest potential disease-modifying activity with imetelstat by reducing the malignant clones driving the disease. In the IMerge Phase 2, no new safety signals were identified, and the most frequent treatment emergent adverse events were cytopenias, which were reversible and with limited clinical consequence.

“We are pleased that the IMerge Phase 2 data have been published in one of the most prestigious oncology journals, the Journal of Clinical Oncology, and we believe that the publication of these data in JCO represents an increased level of interest from the oncology community,” said Aleksandra Rizo, M.D., Ph.D., Geron’s Chief Medical Officer. “The depth and breadth of transfusion independence achievable with imetelstat treatment, as seen in the IMerge Phase 2, can address the significant anemia burden for lower risk MDS patients. These data support our ongoing registration-enabling IMerge Phase 3 clinical trial in lower risk MDS being conducted at multiple sites around the world, and we are planning for top-line results in the second half of 2022.”

Ongoing IMerge Phase 2/3 Clinical Trial

The IMerge Phase 2/3 trial is a two-part clinical trial of imetelstat in transfusion dependent patients with Low or Intermediate-1 risk, also referred to as lower risk myelodysplastic syndromes (MDS), who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). 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.

The IMerge Phase 2 was an open label, single arm trial to assess the safety and efficacy of imetelstat of a 7.5 mg/kg dose of imetelstat administered as an intravenous infusion every four weeks. The Phase 2 enrolled 57 patients, of which a target patient population of 38 patients were naïve to treatment with a hypomethylating agent (HMA) or
lenalidomide and did not have a deletion 5q chromosomal abnormality (non-del(5q)). 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 IMerge Phase 3 is a double-blind, randomized, placebo-controlled clinical trial with registration intent. The trial is designed to enroll approximately 170 patients with lower risk transfusion dependent MDS who meet the defined target patient population identified in the Phase 2 portion of the trial. The IMerge Phase 3 is currently enrolling patients.

About Myelodysplastic Syndromes

MDS is a group of blood disorders in which the proliferation of malignant progenitor cells produces multiple malignant cell clones in the bone marrow resulting in disordered and ineffective production of the myeloid lineage, which includes red blood cells, white blood cells and platelets. Chronic anemia is the predominant clinical problem in patients who have lower risk MDS. Many of these patients become dependent on red blood cell transfusions due to low hemoglobin. Serial red blood cell transfusions can lead to elevated levels of iron in the blood and other tissues, which the body has no normal way to eliminate. Iron overload is a potentially dangerous condition. Studies in patients with MDS have shown that iron overload resulting from regular red blood cell transfusions is associated with lower quality of life, shorter overall survival and a higher risk of developing acute myeloid leukemia.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic myeloid malignancies. Early clinical data suggest imetelstat may have disease-modifying activity through the apoptosis of malignant stem and progenitor cells, which allows potential recovery of normal hematopoiesis. Geron’s imetelstat development program includes two ongoing or planned registration-enabling studies, IMerge, an ongoing Phase 2/3 clinical trial in lower risk myelodysplastic syndromes (MDS), and a planned Phase 3 clinical trial in refractory myelofibrosis (MF) expected to be open for patient screening and enrollment in the first quarter of 2021. Imetelstat has been granted Fast Track designation by the U.S. Food and Drug Administration for both the treatment of patients with non-del(5q) lower risk MDS who are refractory or resistant to an erythropoiesis-stimulating agent and for patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus kinase (JAK) inhibitor treatment.

About Geron

Geron is a late-stage clinical biopharmaceutical company focused on the development and potential commercialization of a first-in-class telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. For more information about Geron, visit www.geron.com.

Use of Forward-Looking Statements

Except for the historical information contained herein, this press release contains forward-looking statements made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such statements, include, without limitation, those regarding: (i) potential disease-modifying activity of imetelstat; (ii) that Geron is planning for IMerge Phase 3 top-line results in the second half of 2022; (iii) that for the planned Phase 3 clinical trial in refractory MF, Geron expects to begin patient screening and enrollment in the first quarter of 2021; and (iv) other statements that are not historical facts, constitute forward-looking statements. These forward-looking statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. These risks and uncertainties, include, without limitation, risks and uncertainties related to: (a) whether the Company overcomes all of the potential delays and other adverse impacts caused by the evolving effects of the COVID-19 pandemic, and overcomes the clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to complete IMerge and open and complete the planned Phase 3 in refractory MF; (b) whether regulatory authorities
permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (c) whether imetelstat is demonstrated to be safe and efficacious in clinical trials; and (d) whether imetelstat demonstrates disease-modifying activity in IMerge and the planned Phase 3 in refractory MF. Additional information on the above risks and uncertainties and additional risks, uncertainties and factors that could cause actual results to differ materially from those in the forward-looking statements are contained in Geron’s filings and periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors” and elsewhere in such filings and reports, including Geron’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Geron disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

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