Geron Announces Fifty Percent Enrollment Milestone in IMerge Phase 3 Clinical Trial in Lower Risk MDS

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IMerge Phase 3 enrollment completion expected in second quarter of 2021

Top-line results expected in second half of 2022

FOSTER CITY, Calif.--(BUSINESS WIRE)-- 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 red blood cell (RBC) transfusion independence (TI) for a consecutive period of eight weeks or longer, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI of at least 24 weeks, or 24-week RBC-TI rate, 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, 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**.

About Myelodysplastic Syndromes (MDS)

Myelodysplastic syndromes 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 blood production. There are approximately 60,000 people in the United States living with the disease and approximately 16,000 reported new cases of MDS in the United States every year. The majority of patients, approximately 70%, fall into the lower risk groups at diagnosis, according to the International Prognostic Scoring System that takes into account the presence of a number of disease factors, such as cytopenias and cytogenetics, to assign relative risk of progression to acute myeloid leukemia (AML) and overall survival.

Chronic anemia is the predominant clinical problem in patients who have lower risk MDS. Due to low hemoglobin, many of these patients become dependent on red blood cell transfusions which can lead to iron overload, higher risk of development AML and poorer overall survival. Currently, no drug therapy has been shown prospectively to alter or delay disease progression.

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 strongly suggest that imetelstat has disease-modifying activity through the apoptosis of malignant stem and progenitor cells, which allows potential recovery of normal hematopoiesis. Current clinical studies of imetelstat include IMerge, an ongoing Phase 2/3 trial in lower risk myelodysplastic syndromes (MDS), and IMpactMF, an upcoming Phase 3 clinical trial in refractory myelofibrosis (MF). Imetelstat has been granted Fast Track designation by the United States 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) that Geron expects enrollment completion in the IMerge Phase 3 trial in the second quarter of 2021 and that top-line results for the IMerge Phase 3 trial to be available in the second half of 2022, as long as enrollment is completed by the end of the first half of 2021; (ii) that the IMerge Phase 3 trial will confirm the meaningful and durable transfusion independence and disease-modifying activity of imetelstat observed in the Phase 2; (iii) that clinical data strongly suggest that imetelstat has disease-modifying activity; (iv) that imetelstat may potentially be commercialized and become a treatment alternative for patients with lower risk MDS; and (v) other statements that are not historical facts, constitute forward looking statements. These 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: (i) whether the Company is able to overcome all the clinical, safety, efficacy, operational, technical, scientific, intellectual property, manufacturing and regulatory challenges to enable: (a) 170 patients to be enrolled in the IMerge Phase 3 and (b) the eventual commercialization of imetelstat; (ii) whether regulatory authorities permit the further development and commercialization of imetelstat on a timely basis, or at all, without any clinical holds; (iii) whether imetelstat is demonstrated to be safe and efficacious in the IMerge Phase 3 clinical trial and other clinical trials; (iv) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (v) whether imetelstat actually demonstrates disease-modifying activity in patients; (vi) whether the Company is able to complete full study enrollment, sufficient treatment and follow-up of patients to assess the primary and secondary endpoints, and conduct necessary analyses to evaluate the benefit-risk profile of imetelstat in lower risk MDS to reach top-line results in the second half of 2022; (vii) whether the Company has sufficient funding to commercialize imetelstat; (viii) whether Geron overcomes all the potential delays, added expense and other adverse impacts caused by the continuing and evolving effects of the novel coronavirus (COVID-19) pandemic; and (ix) whether imetelstat has adequate patent protection and freedom to operate. 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 periodic reports filed with the Securities and Exchange Commission under the heading "Risk Factors," including Geron's quarterly report on Form 10-Q for the quarter ended September 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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