Geron Announces First Patient Dosed in IMerge Phase 3 Clinical Trial in Lower Risk Myelodysplastic Syndromes

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MENLO PARK, Calif., Oct. 10, 2019 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced that the first patient has been dosed in the IMerge Phase 3 clinical trial to evaluate imetelstat, a first-in-class telomerase inhibitor, in lower risk myelodysplastic syndromes (MDS).

“Patients with lower risk MDS become dependent on serial transfusions which leads to iron overload, heart and kidney complications, decreases in quality of life and shorter overall survival. Reducing transfusion burden and achieving transfusion independence remain significant medical needs for this disease,” said Aleksandra Rizo, M.D., Ph.D., Geron’s Chief Medical Officer. “Dosing of the first patient in the IMerge Phase 3 clinical trial is an important step in developing imetelstat as a potential alternative for patients with lower risk MDS who have limited treatment options available today.”

IMerge is a two-part Phase 2/3 clinical trial of imetelstat in transfusion dependent patients with lower risk MDS who are relapsed after or refractory to erythropoiesis-stimulating agents (ESAs). The Phase 3 is planned to enroll approximately 170 patients in a randomized, double-blind, placebo-controlled clinical trial to test the hypothesis that imetelstat improves the rate of red blood cell transfusion independence (TI). A target patient population of non-del(5q) lower risk MDS patients who are naïve to treatment with hypomethylating agents (HMAs) and lenalidomide was identified in Part 1 of IMerge, or the Phase 2 portion, and will be enrolled in the Phase 3. The trial is planned to be conducted at multiple medical centers globally, including North America, Europe, Middle East and Asia. The primary endpoint is 8-week TI rate, which is defined as the proportion of patients achieving transfusion independence during any consecutive eight weeks since entry into the trial. Key secondary endpoints include the rate of transfusion independence lasting at least 24 weeks, or 24-week TI rate, durability of transfusion independence and the amount and relative change in transfusions.

Recently reported Phase 2 data from Part 1 of IMerge suggested meaningful and durable transfusion independence, as well as potential disease-modifying activity and transfusion independence across different MDS patient subgroups, potentially achievable with imetelstat treatment. Many key aspects from Part 1 of IMerge remain the same for the Phase 3, including the primary and secondary endpoints, the dose and schedule of imetelstat administration, the target patient population, and a majority of the participating clinical sites.

Based upon current planning assumptions, Geron expects top-line results for the IMerge Phase 3 clinical trial to be available by mid-year 2022.

To learn more about the IMerge Phase 3 clinical trial and whether the study is enrolling patients in your area, please visit www.clinicaltrials.gov.

About Myelodysplastic Syndromes

Myelodysplastic syndromes are a group of diverse blood disorders that develop because bone marrow cells do not mature into healthy blood cells. Many patients develop chronic anemia, the predominant clinical problem in lower risk MDS, and become dependent on red blood cell transfusions. There are approximately 60,000 people living with the disease in the United States.

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 suppression of malignant progenitor cell clone proliferation, which allows potential recovery of normal hematopoiesis. Ongoing clinical studies of imetelstat consist of IMerge, a Phase 2/3 trial in lower risk myelodysplastic syndromes (MDS), and IMbark, a Phase 2 trial in Intermediate-2 or High-risk 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 the IMerge Phase 3 trial is planned to enroll approximately 170 patients and is planned to be conducted at multiple medical centers globally; (ii) that Geron expects top-line results for the IMerge Phase 3 trial to be available by mid-year 2022; (iii) that imetelstat may have disease-modifying activity; (iv) that imetelstat may be a potential alternative for patients with lower risk MDS and may potentially be commercialized; (v) that recently reported Phase 2 IMerge data suggested meaningful and durable transfusion independence, potential disease-modifying activity, and transfusion independence across different MDS patient subgroups potentially achievable with imetelstat treatment; and (vi) 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 Geron 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 and for multiple medical centers globally to participate in the IMerge Phase 3 clinical trial 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 Geron will be able to successfully retain and recruit key personnel to support its development plans; (vi) whether imetelstat actually demonstrates disease-modifying activity in patients; (vii) whether Geron 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 IMerge Phase 3 top-line results by mid-year 2022; and (viii) 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 June 30, 2019. 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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