# Geron Starts Phase 3 Clinical Trial in Lower Risk Myelodysplastic Syndromes

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MENLO PARK, Calif., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced the opening of patient screening and enrollment for the Phase 3 portion of IMerge to evaluate imetelstat, a first-in-class telomerase inhibitor, in lower risk myelodysplastic syndromes (MDS).

"The start of the Phase 3 portion of IMerge is a significant milestone for Geron and imetelstat," said John A. Scarlett, M.D., Chairman and Chief Executive Officer. "We are hopeful that the Phase 3 will confirm the encouraging results from the Phase 2 portion, and that imetelstat could become a much-needed treatment alternative for patients with lower risk MDS."

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 erythroid stimulating agents (ESAs). The Phase 3 portion 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). The trial is planned to be conducted at multiple medical centers globally, including North America, Europe, Middle East and Asia. The primary efficacy 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.

Many key aspects from the Phase 2 portion of IMerge remain the same for the Phase 3 portion. 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 from the Phase 2 portion, and will be enrolled in the Phase 3. In addition, the primary and secondary endpoints, the dose and schedule of imetelstat administration and many of the clinical sites remain the same as in the Phase 2. Recently reported Phase 2 data highlighted the meaningful and durable transfusion independence, disease-modifying activity, and efficacy responses across MDS patient subgroups potentially achievable with imetelstat treatment.

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

To learn more about IMerge 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. Imetelstat has been granted Fast Track designation by the United States Food and Drug Administration for the treatment of patients with transfusion dependent anemia due to non-del(5q) lower risk MDS who are refractory or resistant to an erythroid stimulating agent.

**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 Phase 3 portion of IMerge 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 potentially

be commercialized; (v) that the Company is hopeful that the Phase 3 IMerge results will confirm the encouraging results from the Phase 2; (vi) that recently reported Phase 2 IMerge data highlighted the meaningful and durable transfusion independence, disease-modifying activity, and efficacy responses across MDS patient subgroups potentially achievable with imetelstat treatment; and (vii) 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 and for multiple medical centers globally to participate in the Phase 3 portion of IMerge 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 Phase 3 IMerge 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 the Company 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 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 Phase 3 IMerge 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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