Geron Reports Updated Results from Phase 2 Portion of IMerge at the 60th American Society of Hematology Annual Meeting

December 3, 2018

Data Support Initiation of Part 2, the Phase 3 portion of IMerge

MENLO PARK, Calif., Dec. 03, 2018 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced that updated results from Part 1 of IMerge, the Phase 2 portion of a Phase 2/3 clinical trial of imetelstat in lower risk myelodysplastic syndromes (MDS), were presented at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, California on December 2, 2018. The oral presentation was made by David Steensma, M.D., Institute Physician at the Dana-Farber Cancer Institute and Associate Professor at Harvard Medical School, and an IMerge clinical investigator. Geron believes these results support initiating the Phase 3 portion of IMerge to address an unmet medical need for patients for whom erythropoiesis stimulating agents (ESAs) are not effective and for whom currently available therapies show only modest efficacy.

"The results from the Phase 2 portion of IMerge presented at ASH highlight imetelstat's broad clinical activity, especially in difficult-to-treat patients, as indicated by the high baseline transfusion burden of the patients enrolled in IMerge. As such, we believe imetelstat could offer a much-needed alternative treatment in lower risk MDS," said John A. Scarlett, M.D., Geron's President and Chief Executive Officer. "We remain committed to developing imetelstat and continue to plan the initiation of the Phase 3 portion of IMerge by mid-year 2019."

IMerge Phase 2/3 Clinical Trial Design

IMerge is a two-part clinical trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk MDS who have relapsed after or are refractory to prior treatment with an ESA. The first part of the trial was originally designed as a Phase 2, open-label, single-arm trial to assess the efficacy and safety of imetelstat. The second part of the trial is planned as a Phase 3 double-blind, randomized, placebo-controlled trial in approximately 170 patients. To be considered for enrollment into IMerge, patients had to be transfusion dependent, requiring ≥4 units of red blood cells (RBC) over 8 weeks prior to entry into the trial. The primary efficacy endpoint of the trial is the rate of RBC transfusion-independence (RBC TI) lasting at least 8 weeks, defined as the proportion of patients without any RBC transfusion during any consecutive 8 weeks since entry into the trial. Key secondary endpoints are the rate of ≥24-week RBC TI and the rate of hematologic improvement-erythroid (HI-E), defined as a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least 8 weeks or a reduction of at least 4 units of RBC transfusions over 8 weeks compared with the prior RBC transfusion burden.

Among the first 32 patients enrolled in the Phase 2 portion of IMerge, an initial cohort of 13 patients, who were non-del(5q) and naïve to HMA and lenalidomide treatment, showed an increased RBC TI rate and durability compared to the overall trial population. Thus, earlier this year, an additional expansion cohort of 25 patients were enrolled who were non-del(5q) and naïve to HMA and lenalidomide treatment in order to increase the experience and confirm the benefit-risk profile of this target patient population.

Clinical Data Presentation

Title: ***Imetelstat Treatment Leads to Durable Transfusion Independence (TI) in RBC Transfusion-Dependent (TD), Non-Del(5q) Lower Risk MDS Relapsed/Refractory to Erythropoiesis-Stimulating Agent (ESA) Who Are Lenalidomide and HMA Naïve*** (Abstract #463)

The oral presentation described combined data with a data cut-off date of October 26, 2018 for the target patient population (n=38) in the Phase 2 portion of IMerge, which includes 13 patients from the initial cohort and 25 patients from the expansion cohort. The initial cohort had a median follow up time of 29 months, and the expansion cohort had a median follow up of almost nine months. As of the data cut-off date, median duration of RBC TI had not been reached for the target patient population. Geron expects further data from the Phase 2 portion of IMerge for the target patient population reflecting longer follow up to be available in 2019 and anticipates submitting such data for presentation at a future medical conference.

Efficacy Highlights for Target Patient Population (n=38):

- 37% (14/38) of patients achieved ≥8-week RBC TI
- 26% (10/38) of patients achieved ≥24-week RBC TI
- Rate of transfusion reduction (HI-E) was 71% (27/38)
- Mean relative reduction of RBC transfusion burden from baseline was 68%
- Broad clinical activity observed

  - Similar 8-week RBC TI was observed in patients with baseline serum erythropoietin (sEPO) levels less than or greater than 500mU/mL
  - 8-week RBC TI consistent across ring-sideroblast (RS) patient subtypes, RS+ and RS-
- Reductions in mutation burden and presence of RS noted among responding patients, suggesting potential disease modifying activity

Safety Summary for Target Patient Population (n=38):

- Cytopenias, particularly neutropenia and thrombocytopenia, were the most frequently reported adverse events which were predictable, manageable and reversible

The slides from the oral presentation at ASH are available on Geron's website at www.geron.com/r-d/publications.

Phase 3 Development Plan for Lower Risk MDS

Based on the combined data from the initial and expansion cohorts for the target patient population in the Phase 2 portion of IMerge, Geron plans to initiate the Phase 3 portion of IMerge after the sponsorship of the ongoing imetelstat clinical trials has been transferred back to Geron. Geron anticipates patient screening and enrollment for the Phase 3 portion of IMerge to begin by mid-year of 2019.

Analyst and Investor Event

On December 10, 2018, Geron will host a webcasted event for analysts and investors. At the event, Dr. Azra Raza, a clinical investigator for IMerge, will reprise the oral presentation made at the ASH Annual Meeting, as well as describe the unmet medical need in lower risk MDS. A live audio webcast of the event will be available on Geron's website, www.geron.com/investors/events. If you are unable to listen to the live presentation, an archived webcast of the event will be available on the Company's website for 30 days.

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 include a Phase 2/3 trial called IMerge in lower risk myelodysplastic syndromes (MDS) and a Phase 2 trial called IMbark in Intermediate-2 to High-risk myelofibrosis. Imetelstat received Fast Track designation from the United States Food and Drug Administration for the treatment of patients with transfusion-dependent anemia due to lower risk MDS who are non-del(5q) and refractory or resistant to an erythroid stimulating agent.

About Geron

Geron is a clinical stage 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 that Geron plans and anticipates that the screening, enrollment and initiation of the Phase 3 portion of IMerge will begin by mid-year 2019; that imetelstat may have disease modifying activity and could offer an alternative treatment in lower risk MDS; and 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 regulatory authorities permit the further development of imetelstat on a timely basis, or at all, to enable patient screening and enrollment of the Phase 3 portion of IMerge to begin by mid-year 2019; (ii) whether imetelstat is safe and efficacious, and whether any past or future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; and (iii) whether the transition of the imetelstat program from Janssen Biotech, Inc. to the Company proceeds on a timely basis to enable the Phase 3 portion of IMerge to begin by mid-year 2019. 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, 2018. 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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