Geron Announces Two Presentations on Imetelstat at Upcoming European Hematology Association Annual Congress

May 16, 2019

MENLO PARK, Calif., May 16, 2019 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced that two abstracts containing clinical data and analyses related to imetelstat, the Company's first-in-class telomerase inhibitor, have been accepted for presentation at the 24th European Hematology Association (EHA) Annual Congress to be held in Amsterdam, the Netherlands, from June 13-16, 2019. The abstracts are available on the EHA website at www.ehaweb.org/congress.

"We appreciate the opportunity to present additional data and analyses at EHA from the ongoing imetelstat clinical trials," said John A. Scarlett, M.D., Geron's Chairman and Chief Executive Officer. "In the Phase 2 portion of IMerge, the 8-week transfusion independence rate increased compared to the data presented last December, supporting the initiation of the Phase 3 portion of IMerge that we plan to open for screening and enrollment by mid-year 2019. For IMbark, the analyses reported in the abstract suggest that treatment with imetelstat is associated with a lower risk of death compared to best available therapy from closely matched real-world data from patients with Intermediate-2 or High-risk myelofibrosis after JAK inhibitor failure."

Updated Efficacy and Safety Data from the Phase 2 Portion of IMerge

Abstract Title: ***Treatment with Imetelstat Provides Durable Transfusion Independence (TI) in Heavily Transfused Non-del(5q) Lower Risk MDS (LR-MDS) Relapsed/Refractory (R/R) to Erythropoiesis Stimulating Agents (ESAs)***

The abstract, accepted for an oral presentation, reports updated efficacy and safety data from 38 patients treated with imetelstat in Part 1 of IMerge, a Phase 2 clinical trial in transfusion dependent, non-del(5q) lower risk myelodysplastic syndromes (MDS) patients who are relapsed or refractory to ESAs and naïve to hypomethylating agent (HMA) and lenalidomide treatment. The primary efficacy endpoint is 8-week RBC-TI rate, which is defined as the proportion of patients achieving red blood cell transfusion independence during any consecutive eight weeks since entry into the trial.

In the preliminary data set used to prepare the abstract, the 8-week RBC-TI rate was 45% (17/38). Based on the most recent clinical cut-off date, used to prepare the IMerge clinical data for the transition of the imetelstat program, the 8-week RBC-TI rate is 42% (16/38), which is an increase of two new responders compared to the 8-week RBC-TI rate of 37% (14/38) reported at the American Society of Hematology Annual Meeting in December 2018. The most frequently reported adverse events were manageable and reversible grade ≥3 cytopenias.

The abstract states these data support initiation of Part 2 of IMerge, the Phase 3 placebo-controlled trial, which is planned to be open for screening and enrollment by mid-year 2019.

Oral Presentation Details:
Session Title: Improvements in MDS Treatment
Session Date: Saturday, June 15
Session Time: 11:30 – 11:45 a.m. CET
Abstract Code: S837

The oral presentation is expected to provide more mature efficacy and safety data for the Phase 2 portion of IMerge.

Analysis of Overall Survival Data from IMbark

Abstract Title: ***Favorable Overall Survival of Imetelstat-Treated Relapsed/Refractory Myelofibrosis Patients Compared with Closely Matched Real World Data***

This abstract, accepted for a poster presentation, provides a new analysis of the overall survival (OS) benefit in patients treated with imetelstat 9.4 mg/kg during the IMbark Phase 2 clinical trial, compared to real-world data (RWD) from patients who had discontinued from a JAK inhibitor (JAKi). For this analysis, historical RWD were collected from a single-center study of patients who had discontinued ruxolitinib. A closely matched cohort of these patients was identified using guidelines for inclusion and exclusion criteria as defined in the IMbark clinical protocol, and consisted of patients who had discontinued JAKi due to lack or loss of response and were subsequently treated with best available therapy (BAT) at the Moffitt Cancer Center. For comparability between the IMbark data and the RWD, several baseline clinical patient characteristics, such as, platelet count, spleen size, time from diagnosis to JAKi therapy discontinuation, MF type and others, were selected to assess the average treatment effect of imetelstat or BAT. Using propensity score approaches, median overall survival in the imetelstat-treated patients from IMbark was calculated to be 30.69 months compared to a median overall survival that was calculated to be 12.04 months in patients treated with BAT at the Moffitt Cancer Center (hazard ratio 0.35, p<.0019). These analyses suggest that treatment with imetelstat is

associated with a lower risk of death compared to BAT from closely matched RWD from patients with Intermediate-2 or High-risk MF after JAKi failure.

Poster Presentation Details:
Session Title: Myeloproliferative neoplasms—Clinical
Session Date: Saturday, June 15
Session Time: 5:30 – 7:00 p.m. CET
Abstract Code: PS1456

In accordance with EHA policies, abstracts submitted to the EHA Annual Congress are embargoed from the time of submission. To be eligible for presentation at the EHA Annual Congress, any additional data or information to be presented at the Annual Congress may not be made public before the presentation. The slide presentation and poster will be available at www.geron.com/r-d/publications following the EHA Annual Congress presentations.

Post-EHA Event with Key Opinion Leaders

On June 25, 2019, Geron plans to host a webcasted event after the EHA Annual Congress. At the event, authors from each of the imetelstat abstracts will reprise the respective presentations from the EHA Annual Congress. A press release with event details, including how to access a webcast link, will be available on Geron's website at the beginning of June.

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: (i) that the Phase 3 portion of IMerge will be open for patient screening and enrollment by mid-year 2019; (ii) that more mature data for the Phase 2 portion of IMerge will be presented at the EHA meeting in June 2019; (iii) that statistical analyses of IMbark data and closely matched RWD suggest treatment with imetelstat is associated with a lower risk of death compared to BAT; (iv) that imetelstat may have disease-modifying activity; 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) availability of more mature data from IMerge for an update at EHA; (ii) whether imetelstat is able to demonstrate a lower risk of death compared to BAT; (iii) whether the Company overcomes all the clinical, safety and efficacy, technical, scientific, manufacturing and regulatory challenges to enable the opening of the Phase 3 portion of IMerge for screening and enrollment by mid-year 2019; (iv) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (v) whether imetelstat is safe and efficacious; (vi) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; and (vii) whether imetelstat demonstrates disease-modifying activity. 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 March 31, 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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