Geron Reports Two Imetelstat Data Presentations at European Hematology Association Annual Congress

June 17, 2019

- Updated 8-week RBC-TI rate for the Phase 2 portion of IMerge increased to 42%, from 37% in December 2018
- Updated 24-week RBC-TI rate for the Phase 2 portion of IMerge increased to 29%, from 26% in December 2018
- Statistical analyses comparing IMbark clinical trial data to closely matched real-world data suggest favorable overall survival with imetelstat compared to best available therapy

MENLO PARK, Calif., June 17, 2019 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced that an oral and a poster presentation of clinical data and analyses related to imetelstat, the Company's first-in-class telomerase inhibitor, were made at the 24th Annual Congress of the European Hematology Association (EHA) held in Amsterdam, the Netherlands on June 15, 2019.

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

"The EHA presentation for the Phase 2 portion of IMerge reported higher efficacy responses from prior reported data for both 8-week and 24-week RBC-TI rates, which highlight the meaningful and durable transfusion independence achievable with imetelstat treatment in heavily transfusion dependent lower risk MDS patients," said Aleksandra Rizo, M.D., Ph.D., Geron's Chief Medical Officer. "These data provide further support for the initiation of the Phase 3 portion of the trial and Phase 3 start-up activities for IMerge are continuing with the goal of opening for screening and enrollment in August 2019."

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)*** (Abstract #S837)

This oral presentation described updated efficacy and safety data as of April 2019 from 38 imetelstat-treated patients in the Phase 2 portion of the IMerge clinical trial with a median follow-up of 15.7 months. All 38 patients represent a target patient population of 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 the rate of red blood cell transfusion independence (RBC-TI) lasting at least eight weeks, or 8-week RBC-TI rate, which is defined as the proportion of patients achieving RBC-TI during any consecutive eight weeks since entry into the trial. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the 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 or a rise in hemoglobin of at least 1.5 g/dL above pretreatment level for at least eight weeks.

Efficacy Summary (n=38):

- 42% (16/38) of patients achieved ≥8-week RBC-TI
- 29% (11/38) of patients achieved ≥24-week RBC-TI
- Median duration of TI was 85.9 weeks (range: 8.0-140.9)
- 68% (26/38) of patients achieved HI-E, or improvement in red blood cell count, as measured by either transfusion reduction or a rise in hemoglobin:
  - All 26 patients had a reduction of at least four RBC units over eight weeks compared with prior transfusion burden
  - 12 of 26 patients had a hemoglobin increase of at least 1.5 g/dL lasting at least eight weeks
- Mean relative reduction in transfusion burden from baseline was 68%

Additional data were presented showing that transfusion independence was observed across different clinical subgroups, as well as in patients with intermediate or poor cytogenetic risk.

Safety Summary:

- No new safety signals were identified. Reversible cytopenias were the most frequent adverse events.

The slide presentation is available on Geron's website at www.geron.com/r-d/publications.

Statistical Analyses of Median Overall Survival in IMbark Compared to Real World Data

"The EHA poster presentation reported the results of statistical analyses in which the months of median overall survival for imetelstat-treated relapsed/refractory MF patients in IMbark was calculated to be more than double that for closely matched patients treated with best available therapy using real-world data," said John A. Scarlett, M.D., Geron's Chairman and Chief

Executive Officer. “The outcomes of these analyses were consistent across two different approaches for propensity score analysis and additional sensitivity analyses, underscoring the robustness of the statistical methodologies applied.”

Abstract Title: ***Favorable Overall Survival of Imetelstat-Treated Relapsed/Refractory Myelofibrosis Patients Compared with Closely Matched Real World Data*** (Abstract #PS1456)

This poster presentation provided a new analysis of overall survival (OS) in relapsed/refractory MF patients treated with imetelstat 9.4 mg/kg in the IMbark Phase 2 clinical trial, compared to OS calculated from real world data (RWD) collected at the Moffitt Cancer Center for patients who had discontinued treatment from ruxolitinib, a JAK inhibitor, and who were subsequently treated with best available therapy (BAT). To make a comparison between the IMbark data and RWD, a cohort from the real-world dataset was identified that closely matched the IMbark patients, using guidelines for inclusion and exclusion criteria as defined in the IMbark clinical protocol, such as platelet count and spleen size.

To mimic the effect of randomization and improve comparability between the IMerge and RWD populations, two different propensity score approaches were used to balance these two populations with respect to baseline covariates and prognostic factors that could have impacted OS outcomes. The calculations from both propensity score approaches resulted in a median OS of 30.7 months for the imetelstat-treated patients from IMbark, which is more than double the median OS of 12.0 months using RWD for patients treated with BAT. The analysis also indicated a 65-67% lower risk of death for the imetelstat-treated patients vs. BAT-treated patients. A sensitivity analysis assessing the impact on OS of subsequent hematopoietic stem cell transplantation showed no substantial differences in median OS calculated for either the imetelstat-treated or BAT-treated patients. The poster presentation concluded that although there are limitations of such comparative analyses between RWD and clinical trial data, favorable OS of imetelstat treatment in this very poor-prognosis patient population warrants further evaluation.

The poster is available at www.geron.com/r-d/publications.

Post-EHA Event with Key Opinion Leaders

On June 25, 2019, Geron will be hosting a webcasted event with authors from each respective data presentation from the EHA Annual Congress who will reprise the presentations from EHA. Information regarding access to the webcast is available at www.geron.com/investors/events.

Current Ongoing Clinical Trials of Imetelstat

Patients currently enrolled in ongoing imetelstat clinical trials continue to be supported through the respective trial protocols, including treatment and follow-up.

Phase 2 Portion of IMerge

IMerge is a two-part Phase 2/3 clinical trial of imetelstat in lower risk MDS. The first part of IMerge was designed as a Phase 2, open label, single arm study to assess the efficacy and safety of imetelstat. 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.

Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the 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 or a rise in hemoglobin of at least 1.5 g/dL above pretreatment level for at least eight weeks. To be eligible for the Phase 2 or Phase 3 portion of IMerge, patients are required to be transfusion dependent, defined as requiring at least four units of packed RBCs over an eight-week period during the 16 weeks before entry into the trial. The Phase 2 portion of IMerge is closed to new patient enrollment.

IMbark

IMbark was designed as a Phase 2 clinical trial to evaluate two starting dose levels of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in patients with Intermediate-2 or High-risk MF who have relapsed after or are refractory to prior treatment with a janus kinase (JAK) inhibitor. The co-primary efficacy endpoints for the trial are spleen response rate and symptom response rate. Key secondary endpoints are safety and overall survival (OS). IMbark is closed to new patient enrollment.

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 consists of a Phase 2/3 trial, called IMerge, in lower risk myelodysplastic syndromes (MDS) and a Phase 2 trial, called IMbark, in Intermediate-2 or 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 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 will be open for patient screening and enrollment in August 2019; (ii) that statistical analyses of IMbark data and closely matched RWD suggest favorable overall survival with imetelstat treatment when compared to closely matched RWD from patients treated with BAT in relapsed/refractory MF; (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) whether imetelstat is able to actually demonstrate a lower risk of death and favorable overall survival compared to BAT in relapsed/refractory MF patients; (ii) whether the comparative analyses between RWD and IMbark clinical trial data described in the poster presentation have limitations and cannot be relied upon as demonstrative; (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 in August 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; (vii) whether the Company will be able to successfully retain or recruit key personnel to support its current and future development plans or to otherwise successfully manage its growth; (viii) the Company's need for additional capital; and (ix) 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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