Geron Announces New Overall Survival Data from IMbark in Imetelstat-Treated Patients with Intermediate-2 or High-Risk Myelofibrosis and Relapsed/Refractory to Janus Kinase Inhibitor Therapy

December 3, 2018

Data Reporting Median Overall Survival of 29.9 Months in High-Dose Arm

Presented at the 60th American Society of Hematology Annual Meeting

MENLO PARK, Calif., Dec. 03, 2018 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced that results from IMbark, a Phase 2 clinical trial of imetelstat treatment in Intermediate-2 or High-risk myelofibrosis (MF) patients who are relapsed or refractory to a Janus Kinase (JAK) inhibitor, were presented at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, California. The oral presentation was made on December 3, 2018 by John Mascarenhas, M.D., Associate Professor of Medicine in the Myeloproliferative Disorders Program of the Tisch Cancer Institute, Division of Hematology/Oncology at the Icahn School of Medicine at Mount Sinai, and an IMbark clinical investigator.

"The IMbark results suggest a meaningful survival outcome in this poor-prognosis, relapsed/refractory MF patient population where there are currently no approved treatments," said John A. Scarlett, M.D., Geron's President and Chief Executive Officer. "We plan to explore potential late-stage development opportunities for imetelstat in MF through discussions with experts in MF and regulatory authorities and expect to provide a decision regarding future development of imetelstat in this patient population by the end of the third quarter of 2019."

Clinical Data Presentation

Title: ***Imetelstat is Effective Treatment for Patients with Intermediate-2 or High-Risk Myelofibrosis Who Have Relapsed on or Are Refractory to Janus Kinase Inhibitor Therapy: Results of a Phase 2 Randomized Study of Two Dose Levels*** (Abstract #685)

IMbark is a Phase 2 clinical trial that evaluated two starting dose levels of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in more than 100 patients with Intermediate-2 or High-risk MF who have relapsed after or are refractory to prior treatment with a JAK inhibitor. The oral presentation highlighted efficacy and safety data from the primary analysis, as well as overall survival data with a clinical cutoff of October 22, 2018 and a median follow up of approximately 27 months.

The co-primary efficacy endpoints for the trial are spleen response rate, defined as the proportion of patients who achieve a ≥35% reduction in spleen volume assessed by imaging; and symptom response rate, defined as the proportion of patients who achieve a ≥50% reduction in Total Symptom Score, at 24 weeks. Key secondary endpoints are safety and overall survival.

For the 9.4 mg/kg dosing arm (n=59), the spleen response rate was 10% (6/59) and the symptom response rate was 32% (19/59). In addition, improvement in bone marrow fibrosis was observed in 25% (15/59) of patients.

The new data presented at ASH indicate that median overall survival (OS) for the 9.4 mg/kg dosing arm was 29.9 months, which suggests a meaningful survival outcome with imetelstat treatment in this poor-prognosis patient population, all of whom met rigorous criteria for having failed or not responded to JAK inhibitor treatment prior to enrollment in the trial. Other observational studies of similar patient populations published in medical literature have reported median OS ranged from approximately 12-14 months.

The safety profile reported for imetelstat-treated patients in IMbark was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. 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.

Future Plan for Imetelstat in Relapsed/Refractory MF

Based on the data from IMbark, Geron plans to discuss the potential future development of imetelstat in MF with MF experts and regulatory authorities. Such discussions will consider how the IMbark results compare with other therapies currently available to MF patients and enable a better understanding of the potential significance of the IMbark results to patients and physicians. The Company expects to outline a decision regarding potential future MF development by the end of the third quarter of 2019.

Analyst and Investor Event

On December 10, 2018, Geron will host a webcasted event for analysts and investors. At the event, Dr. John Mascarenhas will reprise the oral presentation made at the ASH Annual Meeting, as well as describe the unmet medical need in relapsed/refractory MF. 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 to explore late-stage development of imetelstat for treating MF and will provide a decision about this by the end of the third quarter of 2019; that the IMbark results suggest a meaningful survival outcome in the relapsed/refractory MF patient population; that imetelstat may have disease-modifying activity; 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; (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; (iii) whether imetelstat does demonstrate disease-modifying activity; and (iv) whether experts in MF and regulatory authorities agree on and support a development path, if any, for imetelstat in MF. 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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