Geron Announces Fast Track Designation Granted to Imetelstat for Relapsed/Refractory Myelofibrosis

September 30, 2019

MENLO PARK, Calif., Sept. 30, 2019 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN) today announced that the United States Food and Drug Administration (FDA) has granted Fast Track designation to imetelstat for the treatment of adult patients with Intermediate-2 or High-risk myelofibrosis (MF) whose disease has relapsed after or is refractory to janus kinase (JAK) inhibitor treatment, or relapsed/refractory MF. The Fast Track designation includes patients with primary MF and MF developed after essential thrombocythemia or polycythemia vera. This is the same patient population that was studied in Geron's IMbark Phase 2 clinical trial. There are currently no marketed drugs specifically approved for relapsed/refractory MF, representing a significant unmet medical need. Geron plans to conduct an End of Phase 2 meeting with the FDA by the end of the first quarter of 2020 to determine if there is a regulatory path forward for imetelstat in relapsed/refractory MF.

The FDA's Fast Track Program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious conditions and supported by data that demonstrate the potential to address an unmet medical need. Fast Track designation provides opportunities for frequent interactions with FDA review staff, including meetings to discuss the drug's development plan and to ensure the collection of appropriate data needed to support approval. Through the Fast Track Program, a product candidate may be eligible for priority review, if supported by the clinical data, and for the ability to submit completed sections of a New Drug Application (NDA) on a rolling basis as data become available prior to completion of the full application.

About Myelofibrosis

Myelofibrosis (MF), a type of myeloproliferative neoplasm, is a chronic blood cancer in which abnormal or malignant precursor cells in the bone marrow proliferate rapidly, causing scar tissue to form (fibrosis). As a result, normal blood production in the bone marrow is impaired and may shift to other organs, such as the spleen and liver, which can cause them to enlarge substantially. People with MF may have abnormally low or high numbers of red blood cells, white blood cells or platelets in the blood or bone marrow. MF patients can also suffer from debilitating constitutional symptoms, such as fever, weight loss, night sweats, and itching (pruritus). MF patients have shortened survival, and their disease may transform to acute myeloid leukemia.

The number of people living with MF in the United States is estimated at 13,000 patients, with approximately 3,000 new cases diagnosed each year. There are currently only two drugs approved by the FDA for treating MF patients. The most widely used drug therapy for MF has a discontinuation rate of 75% after five years of treatment. Once patients discontinue treatment with this drug due to failure or lack of response, there are no specifically approved therapies, and the median overall survival for these MF patients is approximately 14 to 16 months, representing a significant unmet medical need.

About IMbark

IMbark is 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 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. 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 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 (MF). Imetelstat has been granted Fast Track designation by the United States Food and Drug Administration for both the treatment of patients with non-del(5q) lower risk MDS who are refractory or resistant to an erythropoiesis-stimulating agent and for patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus kinase (JAK) inhibitor treatment.

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 statements in this press release regarding: (i) Geron's plan to conduct an End of Phase 2 meeting with the FDA by the end of the first quarter of 2020; (ii) that imetelstat may have disease-modifying activity; and (iii) 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) Geron may not be able to prepare timely for an End of Phase 2 meeting by the end of the first quarter of 2020; and (ii) imetelstat may not actually demonstrate disease-modifying activity in clinical trials. Additional information on the above-stated 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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