Geron Conducts End of Phase 2 Meeting for Imetelstat in Relapsed/Refractory Myelofibrosis

MENLO PARK, Calif. --(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN) today announced that the Company has conducted an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to discuss the results of the IMbark Phase 2 clinical trial of imetelstat in 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. Based on feedback from the meeting, over the coming months Geron plans to submit several Phase 3 trial design proposals in relapsed/refractory MF and to have further discussions with the FDA regarding potential regulatory approval pathways. The Phase 3 trial proposals will be designed to fully characterize the efficacy, safety, and benefit-risk profile of imetelstat treatment for these patients, as well as to confirm the clinical benefit and disease-modifying potential of imetelstat in this indication. Subsequent to these additional discussions with the FDA, and after considering the timing and resources required, as well as other clinical development opportunities for imetelstat, Geron will make a decision regarding potential late-stage development of imetelstat in relapsed/refractory MF.

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, or fibrosis, to form. 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 circulating red blood cells, white blood cells or platelets, and abnormally high numbers of immature cells in the blood or bone marrow. MF patients can also suffer from debilitating constitutional symptoms, such as drenching night sweats, fatigue, severe itching, or pruritus, abdominal pain, fever and bone pain. The estimated prevalence of MF in the U.S. is approximately 13,000 patients, with an annual incidence of approximately 3,000 patients. Up to 20% of patients with MF develop acute myeloid leukemia.

Approximately 70% of MF patients are classified as having Intermediate 2 or High-risk disease, as defined by the Dynamic International Prognostic Scoring System Plus, or DIPSS Plus, described in a 2011 Journal of Clinical Oncology article. Today, there are two drugs approved in Intermediate-2 or High-risk MF, and both are JAK inhibitors. Currently, no drug therapy is specifically approved for those patients who fail or no longer respond to that treatment, and median survival for such MF patients is only approximately 14 to 16 months, representing a
significant unmet medical need.

**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](http://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 plans to submit several Phase 3 trial designs for relapsed/refractory MF and conduct additional discussions with the FDA; (ii) that Geron’s Phase 3 clinical trial proposals will be designed to fully characterize the efficacy, safety, and benefit-risk profile of imetelstat treatment and confirm the clinical benefit and disease-modifying potential of imetelstat; (iii) that imetelstat may have disease-modifying activity; and (iv) 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 for relapsed/refractory MF before Geron’s submission of any Phase 3 clinical trial designs; (ii) whether Geron decides not to submit any Phase 3 clinical trial designs for relapsed/refractory MF to the FDA; (iii) whether Geron is able to design several, or any, Phase 3 clinical trial designs that the FDA agrees fully characterize the efficacy, safety, and benefit-risk profile of imetelstat treatment and confirm the clinical benefit and disease-modifying potential of imetelstat; and (iv) 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 September 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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