Geron Announces Publication of IMbark Phase 2 Data in Journal of Clinical Oncology

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Results reinforce imetelstat's novel approach to the treatment of myelofibrosis (MF)

Data support ongoing IMpactMF Phase 3 clinical trial

FOSTER CITY, Calif.--(BUSINESS WIRE)--Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced the publication of data from the IMbark Phase 2 clinical trial in the Journal of Clinical Oncology in a paper entitled, “Randomized, Single-Blind, Multicenter Phase II Study of Two Doses of Imetelstat in Relapsed or Refractory Myelofibrosis.” The publication highlights the clinical benefits observed in the study, including symptom response and overall survival, as well as the evidence of disease-modifying activity from biomarker and bone marrow fibrosis assessments.

“We are pleased with the publication of our IMbark Phase 2 data in the high-impact Journal of Clinical Oncology. This highlights the importance of the study data in the advancement of treatment options for MF patients who no longer respond to currently approved JAKi therapies,” said Aleksandra Rizo, M.D., Ph.D., Geron’s Chief Medical Officer. “Imetelstat is a novel telomerase inhibition approach that may alter the course of the disease in patients with myelofibrosis. We look forward to confirming these results in our ongoing IMpactMF Phase 3 clinical trial in refractory MF.”

The publication reports efficacy, safety and biomarker results from the IMbark Phase 2 clinical trial and is available online. As stated in the paper, IMbark tested two imetelstat doses and the 9.4 mg/kg dose every three weeks demonstrated clinical benefits in symptom response rate, with an acceptable safety profile for this poor-risk JAKi relapsed/refractory MF patient population. Biomarker and bone marrow assessments suggested selective effects on the malignant clone.

“In these heavily pre-treated patients with high disease burden whose outcome is dismal, imetelstat treatment resulted in multiple clinical meaningful benefits, including symptom response and potential improvement in overall survival,” said John Mascarenhas, M.D., Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and lead author of the paper. “In addition, the reductions in key driver mutations of the disease that were
also correlated to clinical benefits suggest disease-modifying activity of imetelstat by targeting the underlying MF malignant clones, which differentiates imetelstat from other therapeutic agents currently in development for MF.

Ongoing IMpactMF Phase 3 Clinical Trial

IMpactMF is an open label, randomized, controlled Phase 3 clinical trial with registrational intent. The trial is planned to enroll approximately 320 patients with Intermediate-2 or High-risk myelofibrosis who are refractory to prior treatment with a JAK inhibitor, also referred to as refractory MF. Patients will be randomized to receive either imetelstat or best available therapy. The primary endpoint is overall survival (OS). Key secondary endpoints include symptom response, spleen response, progression free survival, complete response, partial response, clinical improvement, duration of response, safety, pharmacokinetics, and patient reported outcomes.

IMpactMF is currently enrolling patients. For further information about IMpactMF, including enrollment criteria, locations and current status, visit ClinicalTrials.gov/NCT04576156.

About Myelofibrosis (MF)

Myelofibrosis, 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. 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.

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. There are more than 35,000 patients worldwide and more than 13,000 patients in the U.S. living with Intermediate-2 or High-risk MF. The only drug therapies approved for treating these MF patients are JAK inhibitors (JAKi). Currently, MF patients who fail or no longer respond to JAKi treatment have no or limited options, resulting in shortened median overall survival.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic myeloid malignancies. Data from Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in hematologic myeloid malignancies resulting in malignant cell apoptosis and potential disease-modifying activity. 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 inhibitor (JAKi) 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. The Company currently is conducting two Phase 3 clinical trials: IMerge in lower risk myelodysplastic syndromes and IMpactMF in refractory myelofibrosis. 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 such statements, include, without limitation, those regarding: (i) that IMbark clinical data provide strong evidence of disease-modifying activity by imetelstat; (ii) that imetelstat may alter the course of the disease in patients with myelofibrosis; 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: (a) whether regulatory authorities permit the further development and commercialization of imetelstat on a timely basis, or at all, without any clinical holds; (b) whether imetelstat is demonstrated to be safe and efficacious in IMpactMF and other clinical trials; (c) whether any efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (d) whether imetelstat actually demonstrates disease-modifying activity in patients; (e) whether the Company maintains sufficient funding to complete IMpactMF; (f) whether the current or evolving effects of the COVID-19 pandemic and resulting global economic and financial disruptions will materially and adversely impact Geron’s business and business prospects, its financial condition and the future of imetelstat; (g) whether Geron overcomes all of the potential delays and other adverse impacts caused by the current or evolving effects of the COVID-19 pandemic, and overcomes all the enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to complete IMpactMF; and (h) whether imetelstat has adequate patent protection and freedom to operate. 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, 2021. 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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