Geron Announces First Patient Dosed in Investigator-Led Phase 2 IMpress Trial Evaluating Imetelstat in Patients with Relapsed/Refractory AML or Higher Risk MDS

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- First clinical trial to explore the potential of imetelstat in relapsed/refractory acute myeloid leukemia (AML) and higher risk myelodysplastic syndromes (MDS)
- Data from animal pre-clinical models indicated imetelstat prevented expansion of human AML leukemic stem cells and prolonged survival of mice

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced that the first patient has been dosed in the investigator-led Phase 2 IMpress clinical trial evaluating imetelstat, the Company's first-in-class telomerase inhibitor, in patients with acute myeloid leukemia (AM)L, or higher risk myelodysplastic syndromes (MDS), who are relapsed/refractory/intolerant to hypomethylating agents (HMAs).

"This trial is based on multiple preclinical publications that describe the role of telomerase in AML, which have reported that inhibiting telomerase in both mouse and human AML models targets and potentially depletes leukemic stem cells and impairs their leukemic progression," said Faye Feller, M.D., Executive Vice President, Chief Medical Officer of Geron. "We are delighted that the first patient has been dosed in the investigator-led IMpress Phase 2 study, an important first step to understanding the potential impact of imetelstat in relapsed/refractory AML and higher risk MDS."

"Despite some recent advances in the treatment of AML and higher risk MDS, there is still a tremendous unmet need for new agents, especially in the relapsed/refractory setting," said Uwe Platzbecker, M.D., Department of Hematology, Cellular Therapy and Hemostaseology, Leipzig University Hospital, Leipzig, Germany, and Principal Investigator of IMpress. "With the first patient dosed and several in screening, we are pleased that IMpress Phase 2 is underway and look forward to understanding more about the potential efficacy of imetelstat in this rather frail and elderly patient population."

About IMpress Phase 2

IMpress Phase 2 (**NCT05583552**) is an open-label, single-arm, multicenter study aiming to enroll approximately 45 patients AML and higher risk MDS patients who are relapsed, refractory, or intolerant to HMAs. The objective of this trial is to evaluate the efficacy, in terms of hematologic improvement, of imetelstat in this patient population. The primary endpoint of this trial is overall response rate. The combined response assessment criteria for MDS and AML based on IWG 2018 criteria (MDS) and the criteria of the European LeukemiaNet (AML) will be used to define responders. Study sites will be located in Australia, France and Germany.

IMpress Phase 2 is an investigator-led study being led by The European Myelodysplastic Neoplasms Cooperative Group (EMSCO) and Australasian Leukaemia & Lymphoma Group (ALLG).

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic malignancies. Data from non-clinical studies and clinical trials of imetelstat provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in myeloid hematologic malignancies resulting in malignant cell apoptosis and potential disease-modifying activity. Imetelstat has been granted Fast Track designation by the U.S. Food and Drug Administration for both the treatment of adult patients with transfusion dependent anemia due to Low or Intermediate-1 risk MDS that is not associated with del(5q) who are refractory or resistant to an erythropoiesis stimulating agent, and for adult patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus associated kinase (JAK) inhibitor treatment. Geron plans to submit a New Drug Application (NDA) in the U.S. in June 2023 and a Marketing Authorization Application (MAA) in the EU in the second half of 2023 in the lower risk MDS indication.

About Geron

Geron is a late-stage biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize-winning science in a treatment that may alter the underlying drivers of disease. Geron currently has two Phase 3 pivotal clinical trials underway evaluating imetelstat in lower risk myelodysplastic syndromes (LR MDS), and in relapsed/refractory myelofibrosis (MF). To learn more, visit **www.geron.com** or follow us on **LinkedIn**.

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 for lower risk MDS, Geron plans to submit a New Drug Application in the U.S. in June 2023 and a Marketing Authorization Application in the EU in

the second half of 2023; (ii) that imetelstat may alter the underlying drivers of disease and has the potential to demonstrate disease-modifying activity in patients; (iii) that imetelstat has potential efficacy in AML and higher risk MDS patients; and (iv) other statements that are not historical facts, constitute forward-looking statements. These forward-looking 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 the current or evolving effects of the COVID-19 pandemic and/or geopolitical events 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; (b) 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/or geopolitical events, as well as all the enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to have the financial resources for, and to meet expected timelines, planned milestones and expenses; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether any future safety or efficacy results cause the benefit-risk profile of imetelstat to become unacceptable; and (e) whether imetelstat actually demonstrates that it has efficacy in AML and higher risk MDS, alters the underlying drivers of disease and has disease-modifying activity in patients. 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 filings and periodic reports filed with the Securities and Exchange Commission under the heading "Risk Factors" and elsewhere in such filings and reports, including Geron's quarterly report on Form 10-Q for the quarter ended March 31, 2023 and future filings and reports by Geron. 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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