Geron Enters New Innovative Licensing and Access Pathway in the United Kingdom for Imetelstat

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Innovation Passport Designation Awarded to Imetelstat for the Treatment of Lower Risk Myelodysplastic Syndromes

Pathway Intended to Expedite Regulatory Review Process

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage biopharmaceutical company focused on the development and commercialization of treatments for hematologic malignancies, today announced that imetelstat, the Company's first in class telomerase inhibitor, has been granted an Innovation Passport, which is the first prescribed entry point to the Innovative Licensing and Access Pathway (ILAP) launched in the United Kingdom (UK) by the Medicines and Healthcare products Regulatory Agency (MHRA) in January 2021, post-Brexit. The objective of this new licensing and access pathway is to reduce the time to market for innovative medicines. Key benefits of being within ILAP include a 150-day accelerated assessment and rolling review of a Marketing Authorization Application (MAA), as well as opportunities for frequent interactions with the review staff at the MHRA and its partner agencies, including the National Institute for Health and Care Excellence (NICE), to discuss imetelstat's development, regulatory plans and reimbursement plans.

"We are pleased to participate in this new expedited review pathway established by MHRA and look forward to working with them and their partner agencies as we collaborate to bring imetelstat to UK patients," said Sharon McBain, Geron's Vice President, Global Regulatory Affairs. "We are pleased imetelstat met the three qualifying criteria for the Innovation Passport and believe that because of the durable transfusion independence across different patient subgroups and strong evidence of disease-modifying activity observed in our IMerge Phase 2 study, imetelstat's novel telomerase inhibitor approach has the potential to be an important drug in this patient population."

Patients from the IMerge Phase 2 clinical trial achieved durable transfusion independence with imetelstat treatment, including transfusion-free periods greater than one year, irrespective of the disease subgroup, such as ringed sideroblast positive or ringed sideroblast negative. Such durability provides significant and meaningful

clinical benefit to lower risk MDS patients given their chronic anemia and the debilitating impact of serial blood transfusions. In addition, depletion of cytogenetic abnormalities and reductions in key driver mutations associated with lower risk MDS were observed, and these results were also correlated with transfusion independence. Taken together, the durability, molecular and cytogenetic data from IMerge Phase 2 provide strong evidence for disease-modifying activity of imetelstat which has the potential to differentiate it from other currently approved and investigational treatments in lower risk MDS today.

Imetelstat is currently being studied in two Phase 3 clinical trials, IMerge Phase 3 in lower risk MDS and IMpactMF in refractory myelofibrosis. Based upon current planning assumptions, Geron expects top-line results for the IMerge Phase 3 clinical trial to be available at the beginning of January 2023.

About ILAP and Innovation Passport

The Innovation Passport is awarded by the UK's Innovation Licensing and Access Pathway Steering Group, which consists of representatives from MHRA, NICE, the Scottish Medicines Consortium (SMC) and the National Health Service (NHS) England. To enter ILAP and receive an Innovation Passport, an experimental drug needs to meet the following public health and/or patient-centric criteria: (1) the condition is life-threatening or seriously debilitating; (2) the program fulfills at least one of the following: innovative medicine, clinically significant new indication or, it is intended for a special population; and (3) the medicine has the potential to offer benefits to patients. The ILAP aims to accelerate the time to market and facilitate patient access to medicines through the development of a target development profile (TDP) that outlines a unique product-specific roadmap for regulatory and development milestones. Other benefits provided by ILAP include the potential for a 150-day accelerated assessment of a Marketing Authorization Application (MAA) and rolling review. The ILAP also provides opportunities for frequent interactions with the review staff at the MHRA and its partner agencies to discuss the drug's development and regulatory plans, as well as reimbursement.

About IMerge Phase 3

IMerge Phase 3 is a double-blind, randomized, placebo-controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 170 transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (MDS), also referred to as lower risk MDS, who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). The primary endpoint is the rate of red blood cell (RBC) transfusion independence (TI) for any consecutive period of eight weeks or longer, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the rate of hematologic improvement-erythroid (HI-E), defined as a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden.

IMerge Phase 3 is fully enrolled and patient enrollment has been closed. For additional information about IMerge Phase 3, visit **ClinicalTrials.gov/NCT02598661**.

About Myelodysplastic Syndromes

Myelodysplastic syndromes are a group of diverse blood disorders that develop because bone marrow cells do not mature into healthy blood cells. Many patients develop chronic anemia, the predominant clinical problem in lower risk MDS, and become dependent on red blood cell transfusions which leads to iron overload, heart and kidney complications, decreases in quality of life and shorter overall survival. Approximately 70% of MDS patients are categorized in the lower risk groups at diagnosis, according to the International Prognostic Scoring System that assigns relative risk of progression to acute myelogenous leukemia and overall survival by taking into account the presence of a number of disease factors, such as cytopenias and cytogenetics.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in myeloid hematologic 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 myeloid hematologic 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 associated 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 myeloid hematologic 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**.

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 top-line results for IMerge Phase 3 be available at the beginning of January 2023; (ii) that imetelstat has potential disease-modifying activity in

patients and target the malignant stem and progenitor cells of the underlying disease; and (iii) 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 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 overcomes 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 the expected timeline in (i) above; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether imetelstat is demonstrated to be safe and efficacious in IMerge Phase 3; (e) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (f) whether imetelstat actually demonstrates disease-modifying activity in patients and the ability to target the malignant stem and progenitor cells of the underlying disease; (g) whether regulatory authorities require an additional clinical trial for approval even if IMerge Phase 3 meets its primary endpoints; and (h) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials in a timely manner. 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 June 30, 2021 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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