Geron Announces 2019 Accomplishments and Key Development Priorities for 2020

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MENLO PARK, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical development biopharmaceutical company, today announced 2019 accomplishments and key development priorities for 2020. The Company is currently enrolling patients in the Phase 3 IMerge clinical trial of imetelstat in lower risk myelodysplastic syndromes (MDS), and plans to complete enrollment by the end of 2020 with top-line results expected by mid-year 2022.

“From regaining control of the imetelstat program and building an impressive in-house development team to initiating the Company’s first Phase 3 clinical trial, 2019 was a pivotal year for Geron,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “We plan to build on the progress achieved in 2019 as we set our 2020 priorities and finalize our development plans.”

2019 – A Year of Accomplishments

Advancing the Imetelstat Development Program

In May 2019, Geron assumed the imetelstat investigational new drug (IND) sponsorship from Janssen Biotech, Inc. (Janssen), and executed on its 2019 imetelstat development plans, including advancing into late-stage clinical development with the initiation of the Phase 3 IMerge clinical trial in lower risk MDS.

Geron completed the transition of the imetelstat program, including the transfer of the remaining non-clinical, manufacturing and ex-U.S. clinical and regulatory responsibilities from Janssen at the end of September 2019.

Throughout the year, Geron continued to build a solid foundation of extensive hematology-oncology and drug development expertise in key functional areas by attracting senior leadership with extensive experience, including many new development team members and executives with prior experience with imetelstat. This highly capable in-house team will support current and future imetelstat development plans, including plans to explore additional indications, as well as provide the ability to evaluate other hematology-oncology assets to expand the Company’s pipeline in the future.

Commencing the Phase 3 in Lower Risk MDS

In June 2019, Geron presented updated efficacy and safety data for the Phase 2 IMerge clinical trial. The presentation highlighted meaningful and durable transfusion independence, activity across different MDS subtypes and potential disease-modifying activity in lower risk MDS with imetelstat treatment.

Geron achieved a significant milestone in August 2019 with the opening of the Phase 3 IMerge clinical trial for patient screening and enrollment, and the first patient was dosed in October. Many key aspects from the Phase 2 portion of IMerge remained the same for the Phase 3 portion, including the primary and secondary endpoints, the dose and schedule of imetelstat administration, and the target patient population. This trial is an important step in developing imetelstat as a potential alternative for lower risk MDS patients who have limited treatment options.

Regulatory Interactions Related to Myelofibrosis (MF)

The United States Food and Drug Administration (FDA) granted Fast Track designation to imetelstat for the treatment of adult patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus kinase (JAK) inhibitor treatment, or relapsed/refractory MF, in September 2019. 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.

Geron announced that it conducted an End of Phase 2 meeting with the FDA to discuss the results of the IMbark Phase 2 clinical trial of imetelstat in patients with relapsed/refractory MF in December 2019.

Development Priorities for 2020

Geron is setting development priorities that are expected to shape the Company’s 2020 milestones, which will be discussed at a conference call to be held in March 2020 in connection with the announcement of the Company’s year-end 2019 financial results.

Building Momentum in Phase 3 IMerge Clinical Trial in Lower Risk MDS

The Company expects to complete enrollment for the Phase 3 IMerge clinical trial in 2020, which is a key step toward achieving top-line results from the trial by mid-year 2022. As of the beginning of 2020, approximately 40% of the planned clinical sites are open for enrollment.

Determining Potential Late-Stage Development in MF

Based on feedback from the End of Phase 2 meeting, Geron plans to submit several Phase 3 trial design proposals in MF, and to have further discussions with the FDA regarding a potential regulatory approval path. Subsequent to these additional discussions, and after considering the timing and resources required, as well as other clinical development opportunities for imetelstat, Geron plans to make a decision regarding potential late-stage development of imetelstat in MF.

Broadening Imetelstat Program with Additional Hematologic Myeloid Malignancy Indication

Geron expects to expand development of imetelstat within hematologic myeloid malignancies by initiating a proof-of-concept study in an additional indication in 2020.

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 statements of historical fact, the statements contained in this press release are forward-looking statements made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding the expectations, plans, timelines, potential and prospects for imetelstat and Geron, including, without limitation, statements related to: (i) that imetelstat may have disease-modifying activity; (ii) that Geron expects top-line results from the IMerge clinical trial by mid-year 2022; (iii) that Geron plans to discuss a potential regulatory path with the FDA and to make a decision regarding late-stage

development of imetelstat in MF in 2020; (iv) Geron's plan to complete enrollment of IMerge in 2020; (v) that Geron expects to initiate a proof-of-concept study for imetelstat in 2020; (vi) Geron's plans to explore additional indications for imetelstat and to potentially evaluate other hematology-oncology assets; (vii) that imetelstat is a potential alternative for lower risk MDS patients; and (viii) other statements that are not historical facts. 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, the following: (a) regulatory authorities may not permit the further development of imetelstat for MF and/or MDS and/or potential additional indications on a timely basis, or at all, and may impose clinical holds; (b) after interactions with the FDA, Geron may decide not to pursue further development of imetelstat in MF; (c) imetelstat may not demonstrate successful efficacy and safety in clinical trials; (d) Geron may be unable to complete enrollment of IMerge in 2020 due to lack of patients, regulatory holds, insufficient number of sites, unavailability of drug, and other factors and therefore, will be unable to have top-line results by mid-year 2022, if at all; (e) there may be failures or delays in manufacturing sufficient quantities of imetelstat, or other clinical trial materials, in a manner that meets the quality standards of the FDA and other regulatory authorities; (f) Geron may not be able to obtain sufficient funding to support further development of imetelstat; (g) imetelstat may fail to demonstrate in clinical trials that it has disease-modifying activity; and (h) Geron may not acquire an additional product candidate assets and may decide not to pursue any additional indications or start a proof-of-concept study for imetelstat in 2020. Additional information 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 in Geron's quarterly report on Form 10-Q for the quarter ended September 30, 2019 and in subsequent filings on Form 8-K. 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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