



Geron Oral Presentation at Upcoming ASCO Annual Meeting to Highlight Meaningful Continuous Transfusion Independence Observed in Imetelstat-Treated Lower Risk MDS Patients in IMerge Phase 3

May 25, 2023

- Data support NDA submission which is on track for June 2023 to support potential U.S. commercial launch in first half of 2024

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced acceptance of its IMerge Phase 3 abstract as an oral presentation at the upcoming 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. This abstract describes statistically significant positive efficacy and safety data from the pivotal IMerge Phase 3 clinical trial evaluating the Company's first-in-class telomerase inhibitor, imetelstat, in lower risk myelodysplastic syndromes (MDS). These data support the Company's planned New Drug Application (NDA) submission to the U.S. FDA which is on track for June 2023, to support a potential U.S. commercial launch of imetelstat in lower risk MDS in the first half of 2024.

"We believe that imetelstat has the potential to be practice-changing in lower risk MDS based on the unprecedented durability of transfusion independence, as well as broad activity across a range of disease subtypes in IMerge Phase 3," said Faye Feller, M.D., Executive Vice President, Chief Medical Officer of Geron. "We are thrilled that these data will be featured in an oral presentation at ASCO, where we will have a significant medical affairs presence to bring more awareness to the continuing unmet need in lower risk MDS and very much look forward to meaningful engagement with the medical community."

Details for the oral presentation are as follows:

Abstract #: 7004

Title: IMerge: "Results from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Imetelstat in Patients (pts) With Heavily Transfusion Dependent (TD) Non-Del(5q) Lower-Risk Myelodysplastic Syndromes (LR-MDS) Relapsed/Refractory (R/R) to Erythropoiesis Stimulating Agents (ESA)."

Date/Time: June 2, 2023 at 2:12 p.m. CT

Session: "Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allogeneic Transplantation"

Presenter: Amer Methqal Zeidan, Yale School of Medicine

The abstract recaps top-line results from IMerge Phase 3 with a data cut-off of October 2022. As reported in January 2023, the primary endpoint of 8-week transfusion independence (TI) was met with high statistical significance ($P < 0.001$) for imetelstat-treated patients (39.8%) vs. placebo (15.0%). Key secondary endpoint of 24-week TI and hematologic improvement erythroid (HI-E) under 2018 IWG criteria were also met with high statistical significance ($P < 0.001$ for each) for imetelstat-treated patients vs. placebo.

In addition, the rate of 8-week TI was significantly higher with imetelstat vs. placebo across subgroups, including ring sideroblast (RS) negative patients. Median TI duration was significantly longer for imetelstat-treated patients vs. those on placebo (51.6 vs 13.3 weeks, $P < 0.001$). Patients receiving imetelstat had significantly higher mean hemoglobin ($P < 0.001$) and fewer transfusions ($P = 0.042$) over time than those on placebo.

In three of four genes frequently mutated in MDS, variant allele frequency (VAF) reduction was significantly greater in patients treated with imetelstat than placebo: *SF3B1* ($P < 0.001$), *TET2* ($P = 0.032$), *DNMT3A* ($P = 0.019$) and *ASXL1* ($P = \text{NS}$). *SF3B1* VAF reduction correlated with longer TI duration ($P < 0.001$).

No new safety signals were identified. The most common Grade 3/4 adverse events (AEs) were thrombocytopenia and neutropenia, with similar rates of Grade ≥ 3 bleeding and infections on imetelstat and placebo. In patients treated with imetelstat, cytopenias were manageable, of short duration, and $> 80\%$ were reversible to Grade ≤ 2 within 4 weeks.

The abstract concludes that for this lower risk MDS patient population: imetelstat demonstrated statistically significant and clinically meaningful efficacy with high 8- and 24-week TI rates, prolonged TI duration and increased hemoglobin. Also, VAF reduction and its correlation to clinical endpoints support imetelstat's disease-modifying potential, and safety results were consistent with prior reported experience.

Full text of the abstract is available at www.asco.org.

About IMerge Phase 3

The Phase 3 portion of the IMerge Phase 2/3 study is a double-blind, 2:1 randomized, placebo-controlled clinical trial to evaluate imetelstat in patients with IPSS Low or Intermediate-1 risk (lower risk) transfusion dependent MDS who were relapsed after, refractory to, or ineligible for, erythropoiesis stimulating agent (ESA) treatment, had not received prior treatment with either a HMA or lenalidomide and were non-del(5q). To be eligible for IMerge Phase 3, patients were required to be transfusion dependent, defined as requiring at least four units of packed red blood cells (RBCs), over an eight-week period during the 16 weeks prior to entry into the trial. The primary efficacy endpoint of IMerge Phase 3 is the rate of red blood cell transfusion independence (RBC-TI) lasting at least eight weeks, defined as the proportion of patients without any RBC transfusion for at least eight consecutive weeks since entry to the trial (8-week TI). Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks (24-week TI), the duration of TI and the rate of hematologic improvement erythroid (HI-E), which is defined under 2006 IWG criteria as a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. A total of 178 patients were enrolled in IMerge Phase 3 across North America, Europe, Middle East and Asia.

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 IMerge Phase 3, 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 has the potential to demonstrate disease-modifying activity in patients; (iii) that Geron expects a potential commercial launch of imetelstat in lower risk MDS in the first half of 2024; 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 the 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 imetelstat has demonstrated sufficient safety, efficacy and clinical benefit in IMerge Phase 3 to enable regulatory approval; (e) whether any future safety or efficacy results 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) that Geron may need to raise substantial additional capital in order to complete the development and commercialization of imetelstat to meet the expected timelines, planned milestones and expenses; (h) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials that impact a commercial launch in lower risk MDS; (i) whether the follow-up period of 12 months for the IMerge Phase 3 primary analysis was sufficient to demonstrate safety and efficacy, including transfusion independence and clinical benefit, and obtain regulatory approval; and (j) for IMerge Phase 3, the FDA may require Geron to submit additional information or require advisory committee procedures that could cause a regulatory approval, if any, to be delayed. 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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Source: Geron Corporation