



Geron Announces Data Presentations from IMerge Phase 3 Evaluating Imetelstat in Lower Risk MDS at Society of Hematologic Oncology Annual Meeting

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FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced poster presentations of data from IMerge, the Company's Phase 3 clinical trial evaluating its first-in-class investigational telomerase inhibitor imetelstat vs. placebo in patients with lower risk myelodysplastic syndromes (MDS) at the eleventh annual Society of Hematologic Oncology Annual Meeting (SOHO) held in Houston, Texas and virtually.

"For imetelstat-treated patients in the IMerge Phase 3 trial, the durability of transfusion independence, substantial increases in hemoglobin, robust treatment effect across subgroups and improvement in fatigue, along with a manageable safety profile, represent, we believe, an unparalleled clinical benefit in lower risk MDS," said Faye Feller, M.D., Executive Vice President, Chief Medical Officer of Geron. "It was particularly meaningful for these data to be presented at SOHO, where there was a broad array of professionals who touch the lives of patients with lower risk MDS."

The following posters presented at SOHO reflected data presented at the European Hematology Association annual meeting in June 2023:

- MDS-572: Continuous Transfusion Independence with Imetelstat in Heavily Transfused Non-Del(5q) Lower-Risk Myelodysplastic Neoplasms Relapsed/Refractory/Ineligible for Erythropoiesis-Stimulating Agents in IMerge Phase III
- MDS-604: Improvement of Patient-Reported Fatigue in IMerge Phase III Trial of Imetelstat vs Placebo in Heavily Transfused Non-Del(5q) Lower-Risk Myelodysplastic Neoplasms Relapsed/Refractory/Ineligible for Erythropoiesis-Stimulating Agents
- MDS-605: Disease Modifying Activity of Imetelstat in Patients with Heavily Transfused Non-Del(5q) Lower-Risk Myelodysplastic Neoplasms Relapsed/Refractory/Ineligible for Erythropoiesis-Stimulating Agents in IMerge Phase III

The posters are available under the Publications section of Geron's website: <https://www.geron.com/research->

[and-development/publications/](#).

As previously reported, in the IMerge Phase 3 clinical trial, the primary endpoint of 8-week transfusion independence (TI) was significantly higher with imetelstat vs. placebo ($p < 0.001$), with median TI duration approaching one year for imetelstat 8-week TI responders. Mean hemoglobin levels in imetelstat-treated patients increased significantly ($p < 0.001$) over time compared to placebo patients. Statistically significant and clinically meaningful efficacy results were achieved across key MDS subgroups irrespective of ring sideroblast (RS) status, baseline transfusion burden and IPSS risk category. Patient-reported outcomes (PRO) data reported a sustained meaningful improvement in fatigue for imetelstat-treated patients vs. placebo. Consistent with prior imetelstat clinical experience, the most common serious adverse events were primarily short-lived, manageable cytopenias. Treatment with imetelstat vs. placebo led to greater reduction in variant allele frequency (VAF) in multiple genes associated with lower risk MDS, which correlated with clinical endpoints of TI response, longer TI duration and increase in hemoglobin levels, suggesting the potential of imetelstat to modify the disease.

Based on results from the IMerge Phase 3 clinical trial, Geron submitted a New Drug Application for imetelstat in lower risk MDS that was accepted for review by the FDA and assigned a Prescription Drug User Fee Act (PDUFA) action date of June 16, 2024.

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 investigational telomerase inhibitor exclusively owned by Geron and being developed in hematologic malignancies. 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 myelofibrosis (MF) whose disease has relapsed after or is refractory to janus associated kinase (JAK) inhibitor treatment. Imetelstat is currently not approved by any regulatory authority.

About Geron

Geron is a late-stage clinical biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our first-in-class investigational telomerase inhibitor, imetelstat, harnesses Nobel Prize-winning science in a treatment that may alter the underlying drivers of disease. The New Drug Application (NDA) for imetelstat in lower risk myelodysplastic syndromes (LR MDS), based on the results from the Phase 3 IMerge clinical trial, is currently under review by the United States Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of June 16, 2024. Additionally, Geron currently has an ongoing pivotal Phase 3 clinical trial evaluating imetelstat 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) the company's belief that the benefits seen in imetelstat-treated patients in the IMerge Phase 3 trial, along with a manageable safety profile, represent an unparalleled clinical benefit in lower risk MDS; (ii) that FDA has assigned a PDUFA action date of June 16, 2024; (iii) that imetelstat may alter the underlying drivers of disease and has the potential to demonstrate disease-modifying activity in 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 regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (b) whether any future safety or efficacy results cause the benefit-risk profile of imetelstat to become unacceptable; (c) whether imetelstat actually demonstrates that it alters the underlying drivers of disease and has disease-modifying activity in patients; and (d) whether the FDA will extend the PDUFA action date or approve imetelstat for the treatment of transfusion-dependent anemia in patients with lower risk MDS. 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, 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.

Aron Feingold

Vice President, Investor Relations and Corporate Communications

Kristen Kelleher

Senior Manager, Investor Relations

investor@geron.com

media@geron.com

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