

# Geron Announces Publication of Analyses Comparing Real World Data to IMbark Phase 2 in Annals of Hematology

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Analyses Suggest Survival Benefit Associated with Imetelstat Treatment in Comparison to Best Available Therapy

Overall Survival is Primary Endpoint for Ongoing Phase 3 Clinical Trial in Refractory MF

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 the publication in the Annals of Hematology of a paper entitled "Favorable Overall Survival with Imetelstat in Relapsed/Refractory Myelofibrosis Patients Compared with Real World Data," which details statistical analyses comparing data from the Company's IMbark Phase 2 clinical trial to closely matched Real World Data (RWD).

"Across the multiple analyses presented in the publication, the median overall survival for imetelstat-treated patients in our IMbark Phase 2 clinical trial was consistently more than double than the median overall survival for patients treated with best available therapy (BAT) from RWD. For the imetelstat-treated patients, the median overall survival (OS) was approximately 30 months in comparison to approximately 12 months for BAT-treated patients from RWD," said Aleksandra Rizo, M.D., Ph.D., Geron's Chief Medical Officer. "We are pleased with the publication of this important work as these analyses provide us further confidence in the use of OS as the primary endpoint for our ongoing confirmatory IMpactMF Phase 3 trial."

The paper describes several statistical adjustment methods and multiple sensitivity analyses to improve comparability of the data set from the Company's IMbark Phase 2 trial and RWD to mimic the effect of a randomized trial. The authors note consistency in the hazard ratios and statistical significance observed across the multiple analyses, which suggests a survival benefit associated with imetelstat treatment of MF patients after ruxolitinib failure. While acknowledging the limitations of RWD analyses, the authors conclude that the results of these analyses warrant further prospective evaluation of imetelstat in a Phase 3 setting with OS as a primary endpoint.

"The RWD used in this paper was collected from patients treated with BAT at the Moffitt Cancer Center after they

had discontinued treatment from ruxolitinib, a JAK inhibitor," said Rami Komrokji, M.D., Vice Chair, Department of Malignant Hematology at Moffitt Cancer Center. "There is an urgent and unmet need for treatment options with a novel mechanism of action for MF patients who are relapsed/refractory to JAK inhibitors. The reported favorable OS with imetelstat treatment in this as well as in prior publications in this very poor prognosis MF patient population differentiates imetelstat from other therapeutic agents in development for MF today. We are excited to participate in Geron's ongoing IMpactMF clinical trial to confirm these data."

The publication is available online at https://link.springer.com/article/10.1007/s00277-021-04683-w.

## Ongoing IMpactMF Phase 3 Clinical Trial

IMpactMF is an open label, randomized, controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 320 patients with Intermediate-2 or High-risk myelofibrosis who are refractory to prior treatment with a JAK inhibitor, also referred to as refractory MF. Patients will be randomized to receive either imetelstat or best available therapy. The primary endpoint is overall survival (OS). Key secondary endpoints include symptom response, spleen response, progression free survival, complete response, partial response, clinical improvement, duration of response, safety, pharmacokinetics, and patient reported outcomes.

IMpactMF is currently enrolling patients. For further information about IMpactMF, including enrollment criteria, locations and current status, visit ClinicalTrials.gov/NCT04576156.

## **About Myelofibrosis (MF)**

Myelofibrosis, a type of myeloproliferative neoplasm, is a chronic blood cancer in which abnormal or malignant precursor cells in the bone marrow proliferate rapidly, causing scar tissue, or fibrosis, to form. People with MF may have abnormally low or high numbers of circulating red blood cells, white blood cells or platelets, and abnormally high numbers of immature cells in the blood or bone marrow. MF patients can also suffer from debilitating constitutional symptoms, such as drenching night sweats, fatigue, severe itching, or pruritus, abdominal pain, fever and bone pain.

Approximately 70% of MF patients are classified as having Intermediate-2 or High-risk disease, as defined by the Dynamic International Prognostic Scoring System Plus. There are more than 35,000 patients worldwide and more than 13,000 patients in the U.S. living with Intermediate-2 or High-risk MF. The only drug therapies approved for treating these MF patients are JAK inhibitors. Currently, MF patients who fail or no longer respond to JAK inhibitor treatment have no or limited options, resulting in shortened median overall survival.

#### 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 (ESA) 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 the consistency in the hazard ratios and statistical significance observed across multiple analyses suggests a survival benefit associated with imetelstat treatment of MF patients after ruxolitinib failure; (ii) that imetelstat has potential disease-modifying activity; and (iii) other statements that are not historical facts, constitute forward-looking statements. 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, risks and uncertainties related to: (i) whether in IMpactMF imetelstat is able to actually demonstrate a favorable overall survival compared to BAT in refractory MF patients; (ii) that the comparative analyses between RWD and IMbark clinical trial data have limitations and cannot be relied upon as demonstrative; (iii) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (iv) whether imetelstat is safe and efficacious; and (v) whether imetelstat demonstrates disease-modifying activity in IMpactMF. 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 periodic reports filed with the Securities and Exchange Commission under the heading "Risk Factors," including Geron's quarterly report on Form 10-Q for the quarter ended June 30, 2021. 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 forwardlooking 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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