Geron Announces Ten Imetelstat Presentations at Upcoming American Society of Hematology Annual Meeting

11/4/2020

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced that ten abstracts containing clinical data and analyses related to imetelstat, the Company's first-in-class telomerase inhibitor, have been accepted for presentation at the 62nd American Society of Hematology (ASH) Annual Meeting to be held online from December 5-8, 2020. The abstracts are available on the ASH website at **www.hematology.org**.

"We are pleased that all ten of the abstracts we submitted were accepted for presentation at this year's ASH Meeting," said Aleksandra Rizo, M.D., Ph.D., Geron's Chief Medical Officer. "The analyses and data from our Phase 2 IMbark and IMerge trials reported in these abstracts continue to support our ongoing Phase 3 trial in lower risk MDS and our upcoming Phase 3 trial in refractory MF and highlight the clinical benefits and the potential disease-modifying activity achievable with imetelstat treatment."

Lower Risk Myelodysplastic Syndromes (MDS) – Oral Presentation

Abstract Title: Treatment with Imetelstat Provides Durable Transfusion Independence (TI) in Heavily Transfused Non-del(5q) Lower Risk MDS (LR-MDS) Relapsed/Refractory (R/R) to Erythropoiesis Stimulating Agents (ESAs)

Long-term efficacy, safety and biomarker data from 38 patients in the IMerge Phase 2 clinical trial, based on a February 4, 2020 cut-off date and a median follow-up of 24 months, are reported. Consistent with prior presentations, 42% of patients achieved ≥8-week red blood cell transfusion independence (RBC-TI) with a median duration of 20 months, which is the longest so far reported with any agent in relapsed/refractory non-del(5q) lower risk MDS. In addition, 29% of patients were transfusion free more than a year. These data were previously presented at the European Hematology Association (EHA) Annual Congress in June.

Oral Presentation Details
Abstract: #658
Date: Monday, December 7, 2020

Time: 12:45 p.m. PT

Relapsed/Refractory Myelofibrosis (MF) – Three Oral Presentations

Abstract Title: Potential Disease-Modifying Activity of Imetelstat Demonstrated By Reduction in Cytogenetically Abnormal Clones and Mutation Burden Leads to Clinical Benefits in Relapsed/Refractory Myelofibrosis Patients

Results from new analyses on samples from patients in the IMbark Phase 2 clinical trial highlight significant dose-dependent reductions of mutation burden by imetelstat. These results were correlated with improved overall clinical benefits, including higher rates of spleen and symptom responses, bone marrow fibrosis improvement and prolonged overall survival (OS). As concluded in the abstract, the clinical data that suggest improvement in median OS in these patients, together with the data in the abstract, further demonstrate that imetelstat has disease-modifying activity by targeting malignant cells, as evidenced by depletion of cytogenetically abnormal clones and reduction in mutation burden.

Oral Presentation Details
Abstract: #346
Date: Sunday, December 6, 2020
Time: 10:30 a.m. PT

Abstract Title: Telomerase Activity, Telomere Length and hTERT Expression Correlate with Clinical Outcomes in Higher-Risk Myelofibrosis (MF) Relapsed/Refractory (R/R) to Janus Kinase Inhibitor Treated with Imetelstat

Dose-dependent inhibition of the telomerase target, as evaluated by reductions in telomerase activity, human reverse transcriptase (hTERT) levels and telomere length, reported in patients treated with imetelstat in the IMbark Phase 2 clinical trial. Analyses of these biomarker data correlated with clinical responses and longer OS. In addition, dose-dependent reduction in variant allele frequency of driver mutations was noted, indicating that imetelstat targets the underlying clone. These data are consistent with telomere biology in cancer cells and provide evidence for on-target mechanism of action of imetelstat through telomerase inhibition. These results were previously reported as a poster presentation at the EHA Annual Congress in June.

Oral Presentation Details
Abstract: #347
Date: Sunday, December 6, 2020
Time: 10:45 a.m. PT

Abstract Title: **Favorable Overall Survival with Imetelstat Treatment Correlates with Other Clinical Benefits in Intermediate-2 or High-Risk Myelofibrosis Relapsed/Refractory to Janus Kinase Inhibitor**

Overall survival results from IMbark Phase 2 were correlated with clinical benefits observed with imetelstat treatment. The correlation analyses showed a trend of longer OS in patients who achieved symptom response, spleen volume reductions ranging from ≥ 10% to ≥ 35%, and improvement in bone marrow fibrosis, in a dose-dependent manner. These results were previously reported as a poster presentation at the EHA Annual Congress in June.

Oral Presentation Details
Abstract: #53
Date: Saturday, December 5, 2020
Time: 8:00 a.m. PT

Relapsed/Refractory Myelofibrosis (MF) – Three Poster Presentations

Collectively, these poster presentations describe on-target and potential disease-modifying activity of the higher dose of imetelstat from the IMbark Phase 2, and how that relates to better clinical outcomes, including OS, fibrosis improvement; and symptom response, especially in a subset of patients defined as triple negative MF, known to have poor outcome.

Abstract Title**: Correlation Analyses of Imetelstat Exposure with Pharmacodynamic Effect, Efficacy and Safety in A Phase 2 Study in Patients with Higher-risk Myelofibrosis Refractory to Janus Kinase Inhibitor Identified an Optimal Dosing Regimen for Phase 3 Study**

Poster Presentation Details
Abstract: #1283
Date: Saturday, December 5, 2020
Time: 7:00 a.m. – 3:30 p.m. PT

Abstract Title:**Imetelstat Treatment Results in Clinical Benefits, Including Improved Overall Survival, in Patients with Higher-Risk Triple Negative Myelofibrosis Relapsed/Refractory to Janus Kinase Inhibitors (JAKi)**

Poster Presentation Details

Abstract: #3084
Date: Monday, December 7, 2020
Time: 7:00 a.m. – 3:30 p.m. PT

Abstract Title:Treatment with Imetelstat Improves Myelofibrosis-Related Symptoms and Other Patient-Reported Outcomes in Patients with Relapsed or Refractory Higher-Risk Myelofibrosis

Poster Presentation Details
Abstract: #3088
Date: Monday, December 7, 2020
Time: 7:00 a.m. – 3:30 p.m. PT

Myeloproliferative Neoplasms (MPN) –Poster Presentation

Collaborators at UC San Diego report non-clinical data on hTERT and ADAR1 activity in pre-leukemia stem cells and leukemia stem cells (LSC). In various lab experiments and animal models, treatment with imetelstat can prevent pre-leukemia stem cells from evolving into LSCs, suggesting telomerase inhibition may be an effective strategy for preventing MPN progression.

Abstract Title: Imetelstat Inhibits Telomerase and Prevents Propagation of ADAR1-Activated Myeloproliferative Neoplasm and Leukemia Stem Cells

Poster Presentation Details
Abstract: #1264
Date: Saturday, December 5, 2020
Time: 7:00 a.m. – 3:30 p.m. PT

Two Trials in Progress Poster Presentations – Planned Phase 3 in Refractory MF and Ongoing IMerge Phase 3

Abstracts for this category describe innovative clinical trials that have not reached their primary endpoint to provide opportunities for early engagement and collaboration amongst investigators, translational research, clinical and industry investigators, statisticians and regulators.

Abstract Title:A Randomized Open-Label, Phase 3 Study to Evaluate Imetelstat Versus Best Available Therapy in Patients with Intermediate-2 or High-risk Myelofibrosis (MF)

Refractory to Janus Kinase (JAK) Inhibitor

Poster Presentation Details
Abstract: #2194
Date: Sunday, December 6, 2020
Time: 7:00 a.m. – 3:00 p.m. PT

Abstract Title:IMerge: A Phase 3 Study to Evaluate Imetelstat in Transfusion-Dependent Subjects with IPSS Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) that is Relapsed/Refractory to Erythropoiesis-Stimulating Agent (ESA) Treatment

Poster Presentation Details
Abstract: #3113
Date: Monday, December 7, 2020
Time: 7:00 a.m. – 3:30 p.m. PT

In accordance with ASH policies, abstracts submitted to the ASH Annual Meeting are embargoed from the time of submission. To be eligible for presentation at the ASH Annual Meeting, any additional data or information to be presented at the Annual Congress may not be made public before the presentation. The slide presentation and posters will be available at **www.geron.com/r-d/publications** following the ASH Annual Meeting presentations.

Ongoing IMerge Phase 2/3 Clinical Trial

The IMerge Phase 2/3 trial is a two-part clinical trial of imetelstat in transfusion dependent patients with Low or Intermediate-1 risk, also referred to as lower risk myelodysplastic syndromes (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.

The IMerge Phase 2 was an open label, single arm trial to assess the safety and efficacy of imetelstat of a 7.5 mg/kg dose of imetelstat administered as an intravenous infusion every four weeks. The IMerge Phase 2 is no longer enrolling patients, and patients remaining in the treatment phase continue to receive imetelstat treatment, per investigator discretion.

The IMerge Phase 3 is a double-blind, randomized, placebo-controlled clinical trial with registration intent. The trial

is designed to enroll approximately 170 patients with lower risk transfusion dependent MDS who meet the defined target patient population identified in the Phase 2 portion of the trial. The IMerge Phase 3 is currently enrolling patients.

IMbark Phase 2 Clinical Trial

IMbark was designed as a Phase 2 clinical trial to evaluate two dosing regimens of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in patients with Intermediate-2 or High-risk myelofibrosis (MF) who have relapsed after or are refractory to prior treatment with a janus kinase inhibitor (JAKi). The co-primary efficacy endpoints for IMbark were spleen response rate, defined as the proportion of patients who achieve a reduction of at least 35% in spleen volume as assessed by imaging, and symptom response rate, defined as the proportion of patients who achieve a reduction of at least 50% in Total Symptom Score (TSS), at 24 weeks. Key secondary endpoints were overall survival (OS) and safety.

Phase 3 Clinical Trial in Refractory Myelofibrosis

The Phase 3 clinical trial in refractory MF, with OS as the primary endpoint, is an open label 2:1 randomized, controlled clinical trial to evaluate imetelstat in approximately 320 patients with Intermediate-2 or High-risk disease who are refractory to prior treatment with a JAK inhibitor. Patients refractory to a JAK inhibitor are defined as having an inadequate spleen response or symptom response after treatment with a JAK inhibitor for at least six months, including an optimal dose of a JAK inhibitor for at least two months. The control arm of best available therapy excludes JAK inhibitors. 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.

Geron expects the trial to be open for screening and enrollment in the first quarter of 2021.

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 apoptosis of malignant stem and progenitor cells, which allows potential recovery of normal hematopoiesis. Current clinical studies of imetelstat include IMerge, an ongoing Phase 2/3 trial in lower risk myelodysplastic syndromes (MDS), and a planned Phase 3 clinical trial in refractory 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 clinical stage 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 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) imetelstat's potential survival benefit for MF patients who have relapsed after, or are refractory to, prior treatment with a JAKi (relapsed/refractory MF); (ii) that imetelstat may have disease-modifying activity; 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 whether: (i) imetelstat in clinical trials is able to demonstrate an overall survival benefit in patients who have relapsed after, or are refractory to, prior treatment with a JAKi (relapsed/refractory MF); (ii) imetelstat demonstrates disease-modifying activity in clinical trials; (iii) regulatory authorities permit the further development of imetelstat; (iv) imetelstat is safe and efficacious; and (v) any future efficacy or safety results cause the benefit-risk profile of imetelstat to become unacceptable. 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, 2020. 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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