Geron Announces Four Imetelstat Presentations at the Virtual Edition of the European Hematology Association Annual Congress

5/14/2020

MENLO PARK, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today announced that four abstracts containing new clinical data and analyses related to imetelstat, the Company's first-in-class telomerase inhibitor, have been accepted for presentation at the Virtual Edition of the European Hematology Association (EHA) Annual Congress to be held online from June 11-14, 2020. The abstracts are available on the EHA website at **www.ehaweb.org/congress**.

"We are pleased to report very encouraging durability data from the IMerge Phase 2 clinical trial to be presented at the upcoming EHA Annual Congress, including a median duration of 8-week transfusion independence of 88 weeks, which is the longest duration we have reported to date in this trial, and that 29% of patients were transfusion free for more than one year," said John A. Scarlett, M.D., Geron's Chairman and Chief Executive Officer. "We are also pleased that the potential survival benefit associated with imetelstat treatment in the IMbark Phase 2 clinical trial for patients relapsed or refractory to JAK inhibitors was correlated with other clinical benefits observed in the trial, such as symptom response, spleen volume reduction and improvement in fibrosis."

Updated Efficacy and Safety Data from the IMerge Phase 2 Clinical Trial

IMerge is a two-part Phase 2/3 clinical trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (lower risk MDS), who are relapsed after or refractory to prior treatment with erythropoiesis stimulating agents (ESAs). The primary efficacy endpoint of IMerge is 8-week red blood cell transfusion independence (RBC-TI) rate, defined as the proportion of patients not receiving any RBC transfusion during any consecutive eight weeks since entry into the trial. Key secondary endpoints include 24-week RBC-TI rate and the rate of hematologic improvement-erythroid (HI-E), defined 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.

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)

The abstract, accepted for an oral presentation, reports long-term efficacy and safety 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.

Key data highlights from the abstract:

- 75% of the 16 (42%) 8-week RBC-TI responders showed a hemoglobin rise of $\geq$ 3 g/dL during the transfusion-free interval when compared to pretreatment level.
- 12 patients (32%) achieved a 24-week RBC-TI.
- 11 patients (29%) were transfusion free for more than one year, and the longest transfusion free interval was 2.7 years.
- Median RBC-TI duration was 88 weeks, the longest reported to date in the trial.
- HI-E was achieved by 26 patients (68%) with a median duration of 93 weeks.
- Cytogenetic and mutational malignant clone reduction in some patients indicates potential disease-modifying activity of imetelstat.
- Most frequently reported adverse events were manageable and reversible grade $\geq$ 3 cytopenias.

Oral Presentation Details:
Session Title: Novel Treatments for MDS I
Abstract Code: S183
Please check **www.ehaweb.org/congress** for updates regarding the virtual presentation schedule.

New Analyses of Data from 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.

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**

The abstract, accepted for a poster presentation, reports new analyses of data from all 107 patients in both arms (59 patients in the 9.4 mg/kg arm and 48 patients in the 4.7 mg/kg arm) of the IMbark Phase 2 clinical trial with a data cut-off date of February 19, 2020 and a median follow-up of 41.7 months. As of the data cut-off date, median OS was 28.1 months in the 9.4 mg/kg arm and 19.9 months in the 4.7 mg/kg arm. The new analyses report 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. The abstract concludes that these data show dose-related improvements in OS with imetelstat in patients who are relapsed/refractory to JAKi and that the potential survival benefit observed in IMbark with imetelstat was supported by the trend of correlation with other clinical benefits, such as symptom response and spleen volume reduction, as well as fibrosis improvement.

Poster Presentation Details:
Session Title: Myeloproliferative neoplasms—Clinical
Abstract Code: EP1107
Please check **www.ehaweb.org/congress** for updates regarding when EHA e-Poster presentations are scheduled to be available.

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)

The abstract, accepted for a poster presentation, presents new analyses of clinical outcomes, including OS, in triple-negative (TN) patients enrolled in the IMbark Phase 2 clinical trial. Triple-negative MF patients lack the three driver mutations of the disease, JAK2, CALR or MPL, which represents a high-risk molecular signature. These patients have a higher incidence of leukemic transformation and approximately 3-year overall survival from diagnosis when compared to non-TN patients. The abstract concludes that TN patients treated with 9.4 mg/kg in the IMbark Phase 2 clinical trial had better clinical outcomes, such as spleen and symptom response as well as better improvement in fibrosis and OS, when compared to non-TN patients. These data suggest that imetelstat may overcome the poor outcomes expected with TN patients.

Poster Presentation Details:
Session Title: Myeloproliferative neoplasms—Clinical
Abstract Code: EP1101
Please check **www.ehaweb.org/congress** for updates regarding when EHA e-Poster presentations are scheduled to be available.

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

The abstract, accepted for a poster presentation, reports biomarker results and their correlation with the clinical benefits of treatment with imetelstat in patients from the IMbark Phase 2 clinical trial. These results showed dose-dependent inhibition of the telomerase target, as evaluated by reductions in telomerase activity, human reverse transcriptase (hTERT) levels and telomere length, in the IMbark patients treated with imetelstat, and this on-target activity correlated with clinical responses and longer OS. In addition, dose-dependent reduction in variant allele frequency of driver mutations was noted, indicating imetelstat targets the underlying malignant clone. The abstract concludes that these data are consistent with telomere biology in cancer cells and provide evidence for the on-target mechanism of action of imetelstat through telomerase inhibition.

Poster Presentation Details:
Session Title: Myeloproliferative neoplasms—Clinical
Abstract Code: EP1098
Please check **www.ehaweb.org/congress** for updates regarding when EHA e-Poster presentations are scheduled to be available.

In accordance with EHA policies, abstracts submitted to the EHA Annual Congress are embargoed from the time of submission. To be eligible for presentation at the EHA Annual Congress, 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 EHA Annual Congress presentations.

Post-EHA Event with Key Opinion Leaders

In June, Geron plans to host a webcasted event after the EHA Annual Congress. At the event, authors from each of the imetelstat abstracts will reprise the respective presentations from the EHA Annual Congress. A press release with event details, including how to access a webcast link, will be available on Geron's website at the beginning of June 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 apoptosis of malignant stem and progenitor cells, which allows potential recovery of normal hematopoiesis. Clinical studies of imetelstat sponsored by Geron include 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 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) the suggestion that imetelstat may overcome poor outcomes in "triple-negative" relapsed/refractory MF patients; (iii) that imetelstat may have disease-modifying activity; 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 whether: (i) the evolving effects of the COVID-19 pandemic 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; (ii) imetelstat in clinical trials is able to demonstrate (a) an overall survival benefit in relapsed/refractory MF patients, and (b) overcome the poor outcomes in "triple-negative" relapsed/refractory MF patients; (iii) imetelstat demonstrates disease-modifying activity in clinical trials; (iv) regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (v) imetelstat is safe and efficacious; (vi) Geron can accurately project or attain complete enrollment in IMerge or of any potential future clinical trials of imetelstat, whether due to the evolving effects of the COVID-19 pandemic or otherwise; (vii) there occur failures or delays in manufacturing sufficient quantities of imetelstat or other clinical trial materials in a timely manner, whether due to the evolving effects of the COVID-19 pandemic or otherwise; and (viii) 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 annual report on Form 10-K for the year

ended December 31, 2019 and the information included in the Form 8-K filed on May 8, 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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