Geron Reports Imetelstat Oral Presentation at European Hematology Association Congress

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Updated Clinical Data from Original Part 1 of IMerge in Myelodysplastic Syndromes (MDS) Presented

MENLO PARK, Calif., June 18, 2018 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq:GERN) today announced the oral presentation of updated data from the ongoing original Part 1 of IMerge, the Phase 2/3 trial of imetelstat in lower risk myelodysplastic syndromes (MDS). The data was presented by Dr. David Steensma from the Dana-Farber Cancer Institute at the 23rdCongress of the European Hematology Association (EHA) held in Stockholm, Sweden on June 17. Imetelstat is a telomerase inhibitor initially developed by Geron and exclusively licensed to Janssen Biotech, Inc. (Janssen) on a worldwide basis.

"This encore presentation of data from the first 32 patients in Part 1 of IMerge reiterates the encouraging results that prompted the expansion of enrollment of Part 1 to a refined population of lower risk MDS patients who are naïve to lenalidomide and HMAs and who lacked del(5q). We are pleased that there are multiple patients that have been on treatment for over two years," said John A. Scarlett, M.D., Geron's President and Chief Executive Officer. "We look forward to data from the additional patients enrolled earlier this year in the expanded Part 1 of IMerge, as well as Janssen's decision related to the continued development of imetelstat, which is expected by the end of the third quarter."

Clinical Data Presentation

Title: ***Imetelstat in RBC Transfusion-Dependent (TD) Lower Risk MDS Relapsed/Refractory to Erythropoiesis-Stimulating Agents (ESA) (IMerge): Updated Efficacy and Safety*** (Abstract #S1557)

This oral presentation described data as of May 2018 from the first 32 patients enrolled in Part 1 of IMerge with a median follow-up of 95 weeks. To be eligible for the trial, all patients were red blood cell (RBC) transfusion-dependent (TD) at baseline, requiring ≥4 units over 8 weeks prior to entry into the trial. The primary efficacy endpoint is the rate of RBC transfusion-independence (TI) lasting at least 8 weeks, defined as the proportion of patients without any RBC transfusion during any consecutive 8 weeks since entry to the trial. Key secondary endpoints are the rate of 24-week TI 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 8 weeks or a reduction of at least 4 units of RBC transfusions over 8 weeks compared with the prior RBC transfusion burden. IMerge is designed in two parts: Part 1 is a Phase 2, open-label, single-arm trial of imetelstat administered as a single agent by intravenous infusion, and Part 2 is designed to be a Phase 3, randomized, controlled trial. Part 2 has not yet begun.

Efficacy in the Overall Trial Population (n=32):

- 34% (11/32) of patients achieved ≥8-week TI
- Median duration of TI was 23.1 weeks
- Mean relative reduction in transfusion burden from baseline was 60%
- 16% (5/32) of patients achieved ≥24-week TI, with the median TI duration exceeding one year in these patients
- 59% (19/32) of patients achieved an HI-E
- 8-week TI rates were similar among patients with or without ringed sideroblasts (RS) or with serum erythropoietin (EPO) levels greater or less than 500mU/mL

Efficacy in the Lenalidomide and HMA Naïve and Non-Del(5q) Subset (n=13):

- 54% (7/13) of patients achieved ≥8-week TI
- Median duration of TI was 42.9 weeks
- Mean relative reduction in transfusion burden from baseline was 71%
- 31% (4/13) of patients achieved ≥24-week TI
- 69% (9/13) of patients achieved an HI-E

Safety Summary:

- Cytopenias, particularly neutropenia and thrombocytopenia, were the most frequently reported adverse events which were predictable, manageable and reversible

The slide presentation is available on Geron's website at www.geron.com/r-d/publications.

Based on these data, Part 1 of IMerge was expanded and enrolled 25 additional patients who are naïve to lenalidomide and HMA

treatment and are non-del(5q) to increase the experience and evaluate the benefit-risk profile of imetelstat in this refined target patient population. Data from these additional patients are expected to be available at a future medical conference.

About Imetelstat

Imetelstat (GRN163L; JNJ-63935937) is a potent and specific inhibitor of telomerase that is administered by intravenous infusion. This first-in-class compound, discovered by Geron, is a specially designed and modified short oligonucleotide, which targets and binds directly with high affinity to the active site of telomerase. Preliminary clinical data suggest imetelstat might have disease-modifying activity by inhibiting the progenitor cells of the malignant clones associated with hematologic malignancies in a relatively select manner. Most commonly reported adverse events in imetelstat clinical studies include fatigue, gastrointestinal symptoms and cytopenias. Imetelstat has not been approved for marketing by any regulatory authority.

About the Collaboration with Janssen

On November 13, 2014, Geron entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc., to develop and commercialize imetelstat for oncology, including hematologic myeloid malignancies, and all other human therapeutics uses. Under the terms of the agreement, Geron received an upfront payment of $35 million and is eligible to receive additional payments up to a potential total of $900 million for the achievement of development, regulatory and commercial milestones, as well as royalties on worldwide net sales. All regulatory, development, manufacturing and promotional activities related to imetelstat are being managed through a joint governance structure, with Janssen responsible for these activities.

About Geron

Geron is a clinical stage biopharmaceutical company focused on the collaborative development 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 statements in this press release regarding: (i) that imetelstat might have disease-modifying activity by inhibiting the progenitor cells of the malignant clones associated with hematologic malignancies in a relatively select manner; (ii) future data from expanded Part 1 of IMerge; (iii) the safety and efficacy of imetelstat; (iv) potential receipt by Geron of additional payments up to a potential total of $900 million for the achievement of development, regulatory and commercial milestones, and royalties from sales of imetelstat; (v) the timing of Janssen's decision whether to continue development of imetelstat expected by the end of the third quarter; and (vi) 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 Janssen decides to continue to conduct IMerge and the entire imetelstat program; (ii) whether imetelstat is safe and efficacious and will gain regulatory approval by overcoming all of the clinical safety and efficacy, technical, scientific, manufacturing and regulatory challenges; (iii) whether the FDA or other health authorities permit IMerge to continue to proceed under the existing protocols or any amendments thereto; (iv) whether any future efficacy or safety results may cause the benefit/risk profile of imetelstat to become unacceptable; (v) Geron's dependence on Janssen for the development, regulatory approval, manufacture and commercialization of imetelstat, including the risks that if Janssen were to breach or terminate the collaboration agreement or otherwise fail to successfully develop and commercialize imetelstat and in a timely manner, or at all, Geron would not obtain the anticipated financial and other benefits of the collaboration agreement with Janssen and the clinical development or commercialization of imetelstat could be delayed or terminated; and (vi) whether patent coverage of imetelstat enables Janssen to successfully commercialize imetelstat. Additional information on the above-stated 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 March 31, 2018. 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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