Geron Reports Imetelstat Presentations at American Society of Hematology Annual Meeting

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MENLO PARK, Calif., Dec. 06, 2016 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq:GERN) today announced four presentations of exploratory preclinical and clinical data related to the imetelstat program at the 58th American Society of Hematology (ASH) Annual Meeting and Exposition held in San Diego, California from December 3-6, 2016. The presentations are available on Geron’s website at www.geron.com/presentations.

“The imetelstat data presented at ASH this year indicate the potential application of imetelstat in multiple myeloid malignancies,” said John A. Scarlett, M.D., Geron’s President and Chief Executive Officer. “These presentations reflect the ongoing work by academic scientists, clinical investigators and our colleagues at Janssen to advance the imetelstat program, and support the clinical trials being conducted by Janssen in patients with myelofibrosis and myelodysplastic syndromes, who are in need of new treatment options.”

Oral Presentation

Title: The preclinical efficacy of a novel telomerase inhibitor, imetelstat, in AML - a randomized trial in patient-derived xenografts (Abstract #578)

Academic scientists presented data of imetelstat’s activity in human acute myeloid leukemia (AML) xenograft models. The preclinical data demonstrated that imetelstat prolonged overall survival of AML xenografts derived from nine out of 15 individual patient samples compared to saline-treated controls, with robust responses associated with favorable cytogenetic risk groups and mutations in molecular pathways controlling DNA damage. The effects on normal human hematopoiesis were modest and predominantly seen in the B-lymphocyte lineage with relative preservation of myeloid and stem cell populations. These data build on previously published preclinical work conducted in patient-derived models of AML and suggest potential application of imetelstat in the treatment of AML.

Poster Presentations

Title: Characterization of Disease, Treatment Patterns, and Outcomes of Patients with Myelofibrosis: Analysis of 2 United States Commercial Claims Databases (Abstract #4769)

Janssen presented an analysis of treatment patterns and outcomes of patients with myelofibrosis (MF) diagnosed between 2006 and 2015 from two United States medical health insurance claims databases. The analysis suggests that many MF patients (43%) received no treatment or supportive care, and only a fraction received ruxolitinib in spite of a favorable median overall survival associated with frontline treatment (30 months compared with 22 months for patients receiving other treatments). Among patients who failed or discontinued frontline ruxolitinib, the median overall survival was seven months, which underscores the need for new treatment options for this disease.

Title: Dynamics of Telomere Length Reflect the Clonal Suppression Seen with the Telomerase Inhibitor Imetelstat in Patients with Essential Thrombocythemia (Abstract #1938)

Academic scientists and clinical investigators from the prior Geron-sponsored proof-of-concept study in patients with essential thrombocythemia (ET) presented new clinical data on telomere length dynamics following treatment with imetelstat. The data showed that in 10 out of 13 ET patients, telomere length in granulocytes was higher after nine months of treatment with imetelstat, and the change correlated with the reduction of JAK2V617F mutational burden. These observations suggest that imetelstat may suppress neoplastic clones and favor recovery of normal hematopoiesis in these patients providing further evidence of the potential disease-modifying activity of imetelstat in hematologic myeloid malignancies.

Title: Telomerase Inhibition with Imetelstat Eradicates β-catenin Activated Blast Crisis Chronic Myeloid Leukemia
Stem Cells (Abstract #3065)

Academic scientists presented a preliminary investigation into the potential impact of imetelstat on leukemia stem cells in non-clinical models of chronic myeloid leukemia (CML) in blast crisis. The preclinical data suggest that imetelstat plus dasatinib, a standard treatment for CML, may inhibit self-renewal of blast crisis cells in vitro compared with normal bone marrow progenitors. In mouse xenograft models of blast crisis CML, imetelstat treatment reduced the number of leukemia progenitor cells detected in bone marrow and decreased expression of β-catenin, which is believed to be required for the self-renewal of leukemic stem cells in CML. This is the first report of data to suggest that imetelstat might inhibit proliferation of malignant progenitors in CML.

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 has disease-modifying activity by inhibiting malignant progenitor cell 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. Patients in these studies also experienced elevated liver enzymes, which resolved to normal or baseline in the majority of patients followed after imetelstat treatment was withdrawn. 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) imetelstat having activity in other hematologic myeloid malignancies, including acute myeloid leukemia or chronic myeloid leukemia; (ii) imetelstat treatment suppressing the neoplastic clones underlying the disease in hematologic myeloid malignancies; (iii) the safety and efficacy of imetelstat; (iv) the 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; and (v) 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 imetelstat will succeed in IMbark™ and IMerge™ and potential future clinical trials by overcoming all of the clinical safety and efficacy, technical, scientific, manufacturing and regulatory challenges; (ii) 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; (iii) the fact that Geron may not receive any milestone, royalty or other payments from Janssen because Janssen may terminate the collaboration agreement for any reason; (iv) whether imetelstat is safe and efficacious, and whether any future efficacy or safety results may cause the benefit/risk profile of imetelstat to become unacceptable and (v) whether imetelstat can be applied to any or to multiple hematologic malignancies. 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 September 30, 2016. 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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