Chimerix Presents Updated Results from Phase 2 Clinical Trial of DSTAT in Refractory Myelodysplastic Syndrome and Acute Myeloid Leukemia at American Society of Hematology Annual Meeting

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DURHAM, N.C., Dec. 10, 2019 (GLOBE NEWSWIRE) -- Chimerix, Inc. (Nasdaq: CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, today announced that data relating to its dociparstat sodium (DSTAT) program, formerly known as CX-01, were presented at the 61st American Society of Hematology Annual Meeting, in Orlando, FL.

The poster, titled “Updated Study Results for CX-01, an Inhibitor of CXCL12/CXCR4, With Azacitidine for the Treatment of Hypomethylating Agent Refractory AML and MDS,” was presented by Eric Huselton, M.D., Assistant Professor of Medicine at the University of Rochester on December 9, 2019.

As reported in the published study abstract, 20 patients with refractory myelodysplastic syndrome (MDS) (n = 9) or refractory acute myeloid leukemia (AML) (n = 11) were enrolled of which 15 were considered evaluable for response with a bone marrow biopsy after cycle 2. Patients received a 7-day continuous infusion of DSTAT (CX-01) at a dose of 0.25 mg/kg/hour, and azacitidine 75 mg/m^2 daily days 1-7, in 28-day cycles. The primary objective of this trial was to assess the overall response rate. Half of the patients had high risk cytogenetic abnormalities and 3 had TP53 mutations. Patients had a median of 2 prior lines of therapy (range 1-3) with median of 6 prior cycles of hypomethylating agent (HMA) therapy (range 4-20). Only 4 patients had a confirmed response to prior HMA therapy.

The 15 evaluable patients received a median of 3 cycles of CX-01 and azacitidine (range 2-9). Of 15 evaluable patients, there was 1 CR (complete remission) and 3 bone marrow CRs (mCR, with incomplete peripheral blood count recovery), 9 stable disease, and 2 progressive disease for an overall response rate of 27%. Of the 3 patients with a mCR after cycle 2, two had hematologic improvement of their neutrophil and platelet counts, respectively, by the end of cycle 4. A patient with stable disease also had hematologic improvement in platelets.

The median overall survival of evaluable patients was 221 days. The median overall survival was not significantly different between AML patients at 221 days and MDS patients at 248 days.

“Following a minimum of 4 cycles of prior HMA therapy, one would not expect to observe response to subsequent HMA therapy,” said Dr. Huselton. “These results demonstrate DSTAT’s potential to improve HMA therapy outcomes in terms of both response and overall survival.”

"DSTATs mechanism of action is intended to enhance patient benefit when combined with an active agent, so to observe these results in HMA-refractory patients is promising. In addition to our planned Phase 3 pivotal trial in newly diagnosed AML, this study highlights the potential to develop DSTAT to enhance the benefit of multiple therapies such as azacitidine, in AML and MDS in both front-line and recurrent settings," said Mike Sherman, Chief Executive Officer of Chimerix.

About Chimerix

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. The two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

Dociparstat sodium is a potential first-in-class glycosaminoglycan biologic derived from porcine heparin that has low anticoagulant activity but retains the ability to inhibit activities of several key proteins implicated in the retention and viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1). Mobilization of AML blasts and leukemic stem cells from the bone marrow has been associated with enhanced chemosensitivity and may be a primary mechanism accounting for the observed increases in EFS and OS in Phase 2 with DSTAT versus placebo. Randomized Phase 2 data suggest that DSTAT may also accelerate platelet recovery post-chemotherapy via inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy. BCV is a lipid conjugate DNA polymerase inhibitor in development as a medical countermeasure for smallpox. For further information, please visit the Chimerix website,www.chimerix.com

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