Catalyst Biosciences Announces Publication of Marzeptacog Alfa (Activated) Phase 1 Data in The Journal of Thrombosis and Haemostasis

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SOUTH SAN FRANCISCO, Calif., Sept. 04, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced the peer-reviewed publication of previously reported data from the Phase 1 trial of marzeptacog alfa (activated) (MarzAA) in individuals with hemophilia A or B with or without inhibitors in the *Journal of Thrombosis and Haemostasis*.

The paper, entitled: "Phase 1, single-dose escalating study of marzeptacog alfa (activated), a recombinant factor VIIa variant, in patients with severe hemophilia," details the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single ascending intravenous bolus doses of MarzAA.

Subjects in the international Phase 1 open-label study (NCT01439971) were assigned to single dose MarzAA cohorts (0.5, 4.5, 9, 18 or 30 µg/kg). MarzAA showed linear dose-response PK across the 4.5-30 µg/kg dose range, with a terminal half-life of 3.5 hours. Dose-dependent shortening of activated partial thromboplastin time (aPPT) and prothrombin time (PT), and an increase in peak thrombin, determined with a thrombin generation assay, was also observed. MarzAA was well tolerated at all dose levels and was not associated with dose-limiting toxicity. No treatment-emergent severe or serious adverse events occurred.

"MarzAA showed favorable pharmacological data in this first-in-human study and no potential safety concerns were identified. Together, these results supported further examination of MarzAA for the treatment of hemophilia A or B with inhibitors, particularly via subcutaneous administration," said Ralph Gruppo, M.D., lead study author.

Nassim Usman, Ph.D., chief executive officer of Catalyst, added, "There is currently a significant need for a safe, subcutaneously administered treatment option for individuals with hemophilia A or B with inhibitors, acquired hemophilia and other bleeding disorders. The results of this Phase 1 study support the development of MarzAA to fill this unmet need. We are currently studying the efficacy of daily subcutaneous dosing in an ongoing Phase 2/3 trial of MarzAA in individuals with hemophilia A or B with inhibitors. We recently reported positive interim efficacy data from this trial and look forward to sharing topline results by year end."

About the FVIIa Phase 2/3 Trial
Marzeptacog alfa (activated) (MarzAA) is a potent, subcutaneous Factor VIIa therapy being developed for prophylaxis in hemophilia A or B with inhibitors, acquired hemophilia and other bleeding disorders. The Phase 2/3 open-label, subcutaneous efficacy trial in individuals with hemophilia A or B with inhibitors will evaluate the ability of MarzAA to eliminate, or minimize, spontaneous bleeding episodes. The primary endpoint is a reduction in annualized bleed rate that will be compared with each individual's recorded historical annualized bleed rate as the control. The trial will enroll up to 12 individuals with hemophilia and an inhibitor across approximately ten clinical trial sites globally. MarzAA has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A or B with inhibitors.

About Catalyst Biosciences
Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential for Catalyst's product candidates, including the potential for MarzAA to eliminate, or minimize, spontaneous bleeding episodes in individuals with hemophilia A or B with inhibitors, and its plans for clinical development of MarzAA, including completion of an ongoing Phase 2/3 efficacy trial. . Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that the Company makes, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that the ongoing Phase 2/3 efficacy trial may not replicate the results from earlier studies, that potential adverse effects may arise from the testing or use of MarzAA, including the generation of antibodies, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the Securities and Exchange Commission on August 2, 2018, along with other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

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