Catalyst Biosciences Presents Updated Data from Its Phase 2/3 Trial of Subcutaneous Marzeptacog Alfa (Activated) in Individuals with Hemophilia A or B with Inhibitors at the 12th Annual EAHAD Congress

February 8, 2019

Results from the study demonstrate that subcutaneous MarzAA (FVIIa) significantly reduces both annualized bleed rate and the percentage of days with bleeding

Enrollment in the Phase 2 portion of the trial is complete

SOUTH SAN FRANCISCO, Calif., Feb. 08, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), presented updated interim data from the Phase 2/3 trial of subcutaneous prophylactic Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA) currently being developed for the treatment of hemophilia A or B with inhibitors. The data were delivered in an oral presentation at the 12th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) being held Feb. 6-8, 2019 in Prague.

"The positive data from our clinical trial demonstrate clinical proof-of-concept for MarzAA as a subcutaneous treatment option for individuals with hemophilia A or B with inhibitors," said Dr. Nassim Usman, chief executive officer of Catalyst. "To date, each participant in the trial has experienced a clinically significant reduction in annualized bleed rate and the percentage of days with bleeding, highlighting the potential for MarzAA as a safe and effective subcutaneous treatment to reduce spontaneous bleed rates and improve the quality of life of affected individuals. We are pleased to announce that we have completed enrollment and look forward to providing topline results in the third quarter of 2019."

Dr. Howard Levy, chief medical officer of Catalyst, presented the updated results which include data from a total of 11 subjects. Seven subjects have completed dosing in the trial, two are currently dosing, others are completing screening and enrollment is now complete.

To date, for all enrolled patients, the mean annualized bleed rate (ABR) prior to the trial was 19.0 bleeds per year. All subjects who have completed dosing have had clinically significant reductions in ABR and five experienced no bleeds with individualized dosing of either 30 µg/kg MarzAA or 60 µg/kg MarzAA for 50 days. Six subjects had no spontaneous bleeds at their final dose level. The median proportion of days with bleeding for the seven subjects during the pre-study period was 11.0% and this was significantly reduced to a median of 1.0% during the treatment period ($p = 0.016$). A total of more than 450 days of subcutaneous dosing of MarzAA have been completed with only six localized skin reactions in two subjects, and no anti-drug antibodies to MarzAA have been detected to date.

An additional aim of the study is to examine the quality of life (QOL) of individuals who have inhibitors. Results of the analysis have shown that QOL is measurably worse in those with inhibitors compared with those without inhibitors. Interim results after treatment for 50 days with subcutaneous MarzAA showed an improvement in the QOL of individuals, as measured using the Haemophilia Quality Of Life Questionnaire (Haem-A-QOL) and the Haemophilia Activity List.

A copy of the presentation materials can be accessed on the Events and Presentations section of the Catalyst website.

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. All statements, other than statement of historical facts, including, but not limited to, statements about the potential for MarzAA as a safe and effective subcutaneous treatment to reduce spontaneous bleed rates and increase the quality of life of affected individuals, are forward-looking statements. 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 potential adverse effects may arise from the testing or use of MarzAA, including the generation of antibodies, the requirement to conduct additional clinical trials and the risk that larger trials may not replicate the results of the trials reported here, 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 September 30, 2018 filed with the Securities and Exchange Commission on November 1, 2018, and 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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