Catalyst Biosciences Announces Updated Positive Interim Data at the 2018 Hemophilia Drug Development Summit

August 15, 2018

Data demonstrates continued efficacy of marzeptacog alfa (activated) in two additional subjects

SOUTH SAN FRANCISCO, Calif., Aug. 15, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced updated positive interim data from its Phase 2/3 study of subcutaneous (SQ) prophylactic Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA), being developed for the treatment of hemophilia A or B with inhibitors. The data will be delivered in an oral presentation today at the 2018 Hemophilia Drug Development Summit being held on August 15-16 in Boston.

“The ongoing study of subcutaneous MarzAA for the treatment of hemophilia A or B with inhibitors continues to demonstrate positive interim results, as reflected in the clinical update provided at this year’s Hemophilia Drug Development Summit,” said Nassim Usman, Ph.D., chief executive officer of Catalyst. “We have not observed any bleeds or anti-drug antibodies in the two additional subjects who most recently completed dosing with 30 µg/kg MarzAA, as well as in the previously reported individual who completed 50 days of dosing with 60 µg/kg MarzAA. The data from these three individuals support the efficacy of MarzAA to reduce annualized bleed rates after daily subcutaneous injections. Importantly, to date we have not observed any injection site reactions nor any anti-drug antibodies after more than 200 subcutaneous doses of MarzAA.”

Dr. Howard Levy, chief medical officer of Catalyst, will present the updated interim results from the MarzAA Phase 2/3 trial in which five of up to 12 subjects have been enrolled. Since initial interim data was announced at the ISTH conference in July 2018, in which one subject with a historic annualized bleed rate (ABR) of 26.7 had completed the trial with no bleeds after 50 days of treatment with 60 µg/kg MarzAA, two additional subjects have now completed the trial. One of these subjects, who has a historic ABR of 16.6, had no bleeds during treatment with 30 µg/kg MarzAA for 50 days. No ADAs have been detected to date, with safety data for the final 10 days of dosing still being collected for this subject. The second subject, who has a historic ABR of 15.9, had no bleeds during treatment with 30 µg/kg MarzAA for 44 days. No ADAs have been detected to date.

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

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. 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, Inc.
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 marzeptacog alfa (activated) (MarzAA) to provide prophylaxis therapy in patients with hemophilia A or B with inhibitors, Catalyst’s plans to complete a Phase 2/3 open label trial of this product candidate, and Catalyst’s plans to continue development of this and other product candidates. 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 additional human trials will not replicate the results from earlier trials, including interim data, that potential adverse effects may arise from the testing or use of MarzAA or other Catalyst product candidates, 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, 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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