Catalyst Biosciences Meets the Primary Endpoint of Reduction in Annualized Bleeding Rate in the Phase 2 Trial of Subcutaneous Marzeptacog Alfa (Activated) in Patients with Hemophilia A or B with Inhibitors

July 8, 2019

Subcutaneous MarzAA (FVIIa) prophylaxis reduced the annualized bleeding rate by more than 90% compared with pretreatment

Data presented at the 2019 Congress of the International Society on Thrombosis and Haemostasis

Company to host investor call and webcast on Monday, July 8 at 8:00 a.m. EDT

SOUTH SAN FRANCISCO, Calif., July 08, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced that the Phase 2 trial of its subcutaneous (SQ) Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA) for prophylaxis met the primary endpoint of significantly reducing the annualized bleed rate (ABR) in patients with hemophilia A or B with inhibitors. The study also met all secondary endpoints of safety, tolerability and lack of anti-drug antibody or inhibitor formation. The results were presented in an oral presentation at the 2019 Congress of the International Society on Thrombosis and Haemostasis on July 7, 2019, in Melbourne, Australia by Johnny Mahlangu, M.D., Professor of haematology, faculty of health sciences, head of the School of Pathology at the University of Witwatersrand in Johannesburg, South Africa, and a principal investigator in the trial.

"The results from the Phase 2 trial of MarzAA showed that SQ MarzAA achieved statistical significance in the study's primary efficacy endpoint, with an excellent reduction in annualized bleeding rates," said Dr. Nassim Usman, Chief Executive Officer of Catalyst Biosciences. "Reducing the median bleeds to zero with daily SQ prophylactic MarzAA therapy clearly demonstrated improved prophylactic therapy for patients with hemophilia A or B with inhibitors and the potential for leading normal active lives."

Daily SQ administration for 50 days at an individual's final dose of MarzAA significantly reduced the mean 6-month pre-study ABR from 19.8 to 1.6 during treatment ($p<0.01$). Additionally, the Proportion of Days with Bleeding (PDB), was significantly reduced from a 6-month pretreatment mean of 12.3% to 0.8% during treatment ($p<0.01$). The median ABR and PDB were both reduced to zero during treatment, with seven of nine subjects experiencing no bleeds, either traumatic or spontaneous, at their final dose level. Subcutaneous treatment with MarzAA was safe and well-tolerated. Six mild to moderate localized skin reactions were observed in 2 subjects. No anti-drug antibodies or inhibitors to MarzAA were detected after administration of a total of 517 SQ doses. Subcutaneous administration prolonged the half-life of MarzAA to 16.6 hours so that trough levels of MarzAA before the next SQ dose were sufficient to provide bleed prevention.

The Phase 2 open-label trial in patients with hemophilia A or B with inhibitors was designed to evaluate the efficacy of MarzAA in reducing total bleeding episodes. The primary endpoint was to assess the effect of MarzAA on annualized bleed rate at the final dose level, with each patient's historic annualized bleeding rate serving as his own control. MarzAA has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A or B with inhibitors.

Catalyst also presented three posters at the ISTH conference. Dr. Howard Levy, Chief Medical Officer, presented data on assessment of quality of life parameters from the Phase 2 MarzAA trial described above. Dr. Grant Blouse, Vice President of Translational Research, presented a comprehensive *in silico* and *in vitro* immunogenicity risk assessment of the Company's next-generation engineered SQ coagulation Factor IX (FIX) dalcinonacog alfa (DalcA) compared with wildtype FIX. Dr. Mahlangu presented the trial design of the ongoing Phase 2b study of DalcA.

A copy of the presentation materials can be accessed on the Events and Presentations section of the Catalyst website. Catalyst will host an investor call on Monday, July 8, at 8:00 a.m. EDT.

Conference Call Details
The management team will host a conference call for investors on Monday, July 8, 2019, at 8:00 a.m. EDT to discuss the MarzAA and DalcA data presented at ISTH. Conference call, webcast and post-conference call replay details are as follows:

Domestic:	+1.877.425.9470
International:	+1.201.389.0878
Conference ID:	13691678
Webcast link:	http://public.viavid.com/index.php?id=134914

A webcast replay will be available for 30 days following the live event.

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. 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 use of MarzAA as a prophylactic therapy for patients with hemophilia A or B with inhibitors, clinical trial results, the absence of adverse events or inhibitor antibodies in patients treated with MarzAA, and immunogenicity risks of DalcA. 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, including, but not limited to, the risk that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of MarzAA or DalcA, including the generation of antibodies, which has been observed in patients treated with DalcA, 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 filed with the Securities and Exchange Commission on May 2, 2019, and in 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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