Catalyst Biosciences Announces Updated Positive Interim Data from Its Phase 2/3 Study of Marzeptacog Alfa (Activated) in Individuals with Hemophilia A or B with Inhibitors

December 1, 2018

Results demonstrate efficacy of subcutaneous prophylaxis with MarzAA, Catalyst's high potency engineered FVIIa

Data presented at 60th American Society of Hematology Annual Meeting & Exposition

SOUTH SAN FRANCISCO, Calif., Dec. 01, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced additional positive interim data from its Phase 2/3 study 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 presented in a poster at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition on December 1, 2018 in San Diego.

"These results support the efficacy of MarzAA as a subcutaneous prophylactic treatment option for individuals with hemophilia A or B with inhibitors," said Nassim Usman, Ph.D., chief executive officer of Catalyst. "We observed that bleeding in individuals with high annualized bleed rates is significantly reduced or eliminated during MarzAA treatment. With these new data from two additional individuals who have successfully completed the trial, we are optimistic about the potential for MarzAA treatment to achieve extremely low annualized spontaneous bleed rates with individualized, subcutaneous daily dosing."

Dr. Howard Levy, chief medical officer of Catalyst, presented the updated results, including the new data from two additional subjects who have completed the Phase 2/3 MarzAA trial. The first subject, who had an annualized bleed rate (ABR) of 15.2, had no bleeds during 50 days of treatment with 30 µg/kg MarzAA. The second subject, who had an ABR of 22.2, experienced a bleed on Day 4 that did not require treatment. The subject continued on the 30 µg/kg dose level, as the bleed occurred within the first five days of dosing when FVIIa levels are still increasing to therapeutic levels and completed the trial with no additional bleeds during the treatment period.

To date, 13 subjects have consented and five have completed dosing in the Phase 2/3 MarzAA trial. These five subjects had an ABR range of 15.2-26.7 before MarzAA treatment. Three participants experienced no bleeds with individualized dosing of either 30 µg/kg or 60 µg/kg MarzAA and two others had clinically significant reductions in ABR. The median proportion of days with bleeding during the pre-study period was 11.9% and this was significantly reduced to a median of 0.5% during the treatment period. Through a total of more than 300 days of subcutaneous dosing, no injection site reactions or anti-drug antibodies to MarzAA have been detected. In one subject, two subcutaneous injections resulted in a mild localized hematoma that resolved without sequelae or treatment. Final data from the study are expected in the first half of 2019.

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

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
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 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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