



## **Catalyst Biosciences Initiates Phase 2/3 Trial of Marzeptacog Alfa (activated) for Prophylaxis in Hemophilia A or B with Inhibitors**

January 4, 2018

*Currently Enrolling Individuals with Hemophilia A or B with Inhibitors*

*Interim Data Expected During the First Half of 2018*

SOUTH SAN FRANCISCO, Calif., Jan. 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 initiation and open enrollment of the Phase 2 part of the Phase 2/3 program of marzeptacog alfa (activated) (MarzAA), a potent, subcutaneously administered, Factor VIIa therapy being developed for prophylaxis in hemophilia A or B with inhibitors.

"For individuals with hemophilia B with inhibitors there are no approved subcutaneous therapies, and a recently approved subcutaneous treatment for hemophilia A with inhibitors has safety concerns," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "With the initiation of this Phase 2 MarzAA trial, Catalyst is now conducting two clinical studies with subcutaneous candidates for individuals with hemophilia, and we are one step closer to potentially providing safe and convenient treatment options using high potency replacement coagulation factors to restore coagulation."

This Phase 2 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 historical annualized bleed rate as the control. Safety and tolerability of daily subcutaneous dosing and potential inhibitor formation will also be monitored. The trial will enroll up to 12 individuals with hemophilia and an inhibitor across approximately ten clinical trial sites globally. Interim data is expected to be announced in the first half of 2018.

### **About Marzeptacog Alfa (activated)**

Marzeptacog alfa (activated) (MarzAA) is a potent, subcutaneous Factor VIIa therapy being developed for prophylaxis in hemophilia A or B with inhibitors. Phase 1 data in 25 individuals with severe hemophilia, with and without inhibitors, showed that MarzAA demonstrated excellent safety and tolerability. A six- to nine-fold improvement in potency and duration of effect has been documented in preclinical studies compared with NovoSeven®. 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**

Catalyst is a clinical-stage biopharmaceutical company focused on 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 <http://www.catalystbiosciences.com/>.

### **Forward-Looking Statement**

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statement of historical facts, included in this press release regarding our strategy, the potential uses and benefits of marzeptacog alfa (activated) and development plans for this product candidate are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Catalyst's clinical trial timelines, including the anticipated patient enrollment of the Phase 2/3 trial of marzeptacog alfa (activated), the anticipated announcement of interim trial results in the first half of 2018, and the potential uses and benefits of subcutaneously dosed marzeptacog alfa (activated). Actual results or events could differ materially from the plans and expectations and projections disclosed in these forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Catalyst makes, including, but not limited to, the risk that trials and enrollment may be delayed and may not have satisfactory outcomes, that human trials will not replicate the results from preclinical studies, that subcutaneous dosing of marzeptacog alfa (activated) may not provide a therapeutic response, that potential adverse effects may arise from the testing or use of Catalyst's products, including the generation of antibodies or inhibitors, the risk that costs required to develop or manufacture Catalyst's products will be higher than anticipated, competition, and other factors described in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q filed with the SEC on November 2, 2017. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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