Catalyst Biosciences Receives Orphan Designation from the European Commission for Marzeptacog Alfa (Activated)

April 1, 2019

Dosing successfully completed in the Phase 2 portion of the Phase 2/3 MarzAA trial for the treatment of hemophilia A or B with inhibitors

SOUTH SAN FRANCISCO, Calif., April 01, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq: CBIO) today announced that the European Commission has awarded orphan designation of its Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA) for the treatment of haemophilia B (with or without inhibitors).

Catalyst has also completed dosing in the Phase 2 portion of the Phase 2/3 subcutaneous trial of MarzAA for the treatment of hemophilia A or B with inhibitors. Nine subjects successfully completed dosing and top-line results will be presented in the third quarter of 2019.

“Orphan designation is another important acknowledgement of the significant benefits of subcutaneous MarzAA and will complement our orphan drug designation already granted in the U.S. by the Food and Drug Administration,” said Nassim Usman, Ph.D., chief executive officer of Catalyst. “We have completed dosing in the Phase 2 portion of the Phase 2/3 trial for the treatment of hemophilia A or B with inhibitors and have clearly demonstrated efficacy as measured by greater than 90% reduction in annualized bleed rate (ABR), as well as bleeding density. We expect to present top-line results from the study in the third quarter of 2019. We also plan to initiate a Phase 3 MarzAA registrational study in 2020 and believe that subcutaneous MarzAA has significant commercial potential in the $2.2 billion hemophilia inhibitor market.”

About 30 million people living in the European Union (EU) suffer from a rare disease. The European Medicines Agency (EMA) plays a central role in facilitating the development and authorization of medicines for rare diseases. Orphan medicinal products, orphan designation, is given to products that are intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, where prevalence of the condition in the EU is less than 5 in 10,000 persons and where the product represents a significant benefit over existing treatments. Orphan designation benefits include protocol assistance, reduced EU regulatory filing fees and 10 years of market exclusivity. Designated orphan medicines are also eligible for conditional marketing authorization. Detailed information on orphan designation can be found here.

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 to treat patients with hemophilia B with or without inhibitors, and plans to announce top-line results for the Phase 2/3 trial in the third quarter of 2019 and to initiate a Phase 3 MarzAA registration study in 2020 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 that ongoing or planned trials may be delayed and may not have satisfactory outcomes, that such trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of the Company’s products, including the generation of antibodies, and other risks described in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 8, 2019, 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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