Catalyst Biosciences Completes Manufacturing Agreements for its Novel Factor VIIa Product, Marzeptacog alpha (activated)

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-- Manufacturing capabilities in place for process development, clinical and commercial manufacture of marzeptacog alfa (activated) --

SOUTH SAN FRANCISCO, Calif., Dec. 19, 2016 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced it has secured all rights to the manufacturing process for marzeptacog alfa (activated) (formerly known as CB 813d) from Wyeth LLC, a wholly-owned subsidiary of Pfizer. Marzeptacog alfa (activated) is a next-generation Factor VIIa product that was designed to allow for the effective, long-term, subcutaneous prophylaxis in hemophilia patients with inhibitors. Catalyst has successfully completed an intravenous Phase 1 clinical trial of marzeptacog alfa (activated) in patients with severe hemophilia A and B with and without inhibitors and has demonstrated the feasibility of subcutaneous dosing in preclinical models.

In addition, the Company announced that it has signed a drug product fill-finish manufacturing services agreement with Symbiosis Pharmaceutical Services Limited for marzeptacog alfa (activated) for clinical trial applications. This agreement, and the previously announced drug substance manufacturing agreement with CMC Biologics, provides Catalyst Biosciences with complete manufacturing capabilities to enable cGMP manufacturing of marzeptacog alfa (activated).

"We are delighted to have successfully concluded our agreement with Wyeth LLC that gives us full rights to use Wyeth's commercial scale manufacturing processes, materials, know-how and intellectual property for marzeptacog alfa (activated). With the Wyeth, CMC Biologics and Symbiosis Pharmaceutical Services agreements in place we are now prepared to initiate an efficacy study in 2017 and have a commercial scale manufacturing process in place," said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst.

Catalyst is focused on the prevention of spontaneous bleeding in hemophilia through the development of clotting factors that may be injected subcutaneously, including marzeptacog alfa (activated). The Company is also developing CB 2679d/ISU304, a next-generation coagulation Factor IX variant that Catalyst, with its collaboration partner, ISU Abxis, plan to initiate a Phase 1/2 proof-of-concept study in individuals with hemophilia B in the first quarter of 2017.

About Hemophilia and Factor Replacement Therapy
Hemophilia, for which there is no cure, is a rare but serious bleeding disorder that results from a genetic or an acquired deficiency of a protein required for normal blood coagulation. There are two major types of hemophilia, A and B, that are caused by alterations in Factor VIII or Factor IX genes, respectively, with a corresponding deficiency in the affected proteins. The prevalence of hemophilia A and B in the United States is estimated to be around 20,000 people, with more than 400,000 cases worldwide. Individuals with hemophilia suffer from spontaneous bleeding episodes as well as substantially prolonged bleeding times upon injury. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in permanent, disabling joint damage and can become life threatening. Treatment usually involves management of acute bleeding episodes or prophylaxis through factor replacement therapy by infusion of patients' missing Factor VIII or IX. With the frequent infusion schedule of current therapies, adherence is difficult. In addition, convenient access to peripheral veins is often a problem, and many children require use of central venous access devices, with the concomitant risks of infection and thrombosis.

About Factor VIIa
Marzeptacog alfa (activated) is a next-generation Factor VIIa that successfully completed a Phase 1 clinical trial in severe hemophilia A and B with and without inhibitors. Marzeptacog alfa (activated) is being developed for the prophylactic treatment of severe hemophilia patients with inhibitors. Marzeptacog alfa (activated) was designed to combine higher clot-generating activity at the site of bleeding and improved duration of action.

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. Catalyst's most advanced program is an improved next-generation coagulation Factor VIIa variant, marzeptacog alfa (activated), that has successfully completed an intravenous Phase 1 clinical trial in individuals with severe hemophilia A or B. Catalyst is also developing a next-generation Factor IX variant, CB 2679d/ISU304, that is in advanced preclinical development. For more information, please visit www.catbio.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, included in this press release regarding our strategy, future operations, and plans 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 benefits of the Wyeth and CBC Biologics agreements, the anticipated initiation of an efficacy study for marzeptacog alfa (activated) in 2017 and of a Phase 1/2 clinical trial for Factor IX CB 2679d/ISU304 in the first quarter of 2017, and the potential uses and benefits of subcutaneously dosed marzeptacog alfa (activated) and CB 2679d/ISU304. 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 Catalyst makes, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that human trials will not replicate the results from animal studies, that potential adverse effects may arise from the testing or use of Catalyst's products, including the generation of antibodies, the risk that costs required to develop or manufacture Catalyst's products will be higher than anticipated, competition and other factors that affect our ability to successfully develop, manufacture and commercialize our product candidates described in the "Risk Factors" section of the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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