Catalyst Biosciences' Factor IX Granted Orphan Drug Designation in Europe

June 28, 2017

-- Orphan Medicine Designation granted by European Commission for CB 2679d/ISU304, a next-generation Factor IX for subcutaneous prophylactic treatment for individuals with Hemophilia B --

SOUTH SAN FRANCISCO, Calif., June 28, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced that the European Commission has granted orphan medicinal product designation to CB 2679d/ISU304, a clinical stage drug candidate for hemophilia B.

"The many benefits of orphan medicinal product designation include the potential for conditional marketing authorization and ten years of market exclusivity," said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. "Hemophilia B is life-threatening and can be chronically debilitating for afflicted individuals. With this important designation, we are optimistic that CB 2679d may provide a significant benefit over existing treatments that rely on frequent intravenous infusions by providing simpler subcutaneous dosing and potentially, normalization of FIX activity."

Earlier this month, the Company announced that its collaborator, ISU Abxis completed dosing in the first of up to five patient cohorts in a Phase 1/2 proof-of-concept study in individuals with severe hemophilia B. The Companies plan to have data from the trial by the end of 2017.

About Orphan Designation
Orphan designation in the European Union (EU) 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; 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.

About Factor IX
CB 2679d/ISU304 is a next-generation coagulation Factor IX variant that is IND-approved in South Korea. Catalyst believes that CB 2679d/ISU304 may allow for subcutaneous prophylactic treatment of individuals with hemophilia B. Learn more about Factor IX.

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. Individuals with hemophilia suffer from spontaneous bleeding episodes as well as substantially prolonged bleeding times upon injury. Learn more about hemophilia.

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, 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, 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 completion of a Phase 1/2 clinical trial for Factor IX CB 2679d/ISU304, and the potential uses and benefits of subcutaneously dosed 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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