Catalyst Biosciences Granted FDA Orphan Drug Designation for Subcutaneous Recombinant Human Factor IX Variant for Treatment of Hemophilia B

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-- Orphan drug designation provides marketing exclusivity if approved by FDA --

SOUTH SAN FRANCISCO, Calif., Sept. 26, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) for CB 2679d/ISU304, Catalyst's highly potent subcutaneous next-generation recombinant human Factor IX variant, for the treatment of hemophilia B.

"Receipt of FDA orphan status will support the development of this promising subcutaneous treatment option for individuals with hemophilia B. Notable benefits of ODD include the potential for seven years of market exclusivity," said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. "Assuming our ongoing clinical development program is successful, this important designation will bolster the rapid availability of CB 2679d for subcutaneous prophylaxis in this life-threatening and chronically debilitating disorder."

In June 2017, the Company announced that the European Commission had also granted orphan medicinal product designation to CB 2679d for hemophilia B. Catalyst and its collaborator, ISU Abxis, are evaluating CB 2679d in a Phase 1/2 proof-of-concept study in individuals with severe hemophilia B. The Companies plan to have interim, top-line results by the end of 2017 and complete trial results in early 2018.

About Orphan Designation
Orphan drug designation is granted by the FDA to drugs and biologics that are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain incentives which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity.

About Factor IX
CB 2679d is a next-generation high-potency coagulation Factor IX variant that is being evaluated in a Phase 1/2 proof-of-concept clinical trial in South Korea. Catalyst believes that CB 2679d 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, the potential uses and benefits of CB 2679d 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 completion of a Phase 1/2 proof-of-concept study for CB 2679d, the plans to disclose interim top-line results from the Phase 1/2 study by the end of 2017 and complete trial results by early 2018 and to report results at upcoming medical conferences, and the potential uses and benefits of subcutaneously dosed CB 2679d. 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 CB 2679d may not replicate potency or duration of blood levels, 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 described in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q filed with the SEC on August 3, 2017. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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