Catalyst Biosciences Announces IND Approval in South Korea for Next-Generation Subcutaneous Factor IX Program

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-- Investigational New Drug (IND) approval from Korean Ministry of Food and Drug Safety represents a key milestone in Catalyst's Factor IX development program --

-- Catalyst's collaborator, ISU Abxis, plans to initiate a Phase 1/2 proof-of-concept study in individuals with severe hemophilia B in the second quarter of 2017 --

SOUTH SAN FRANCISCO, Calif., March 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 Korean Ministry of Food and Drug Safety (MFDS) approved the Investigational New Drug Application (IND) for CB 2679d/ISU304. Hemophilia is a serious bleeding disorder that results in spontaneous bleeding episodes as well as substantially prolonged bleeding times upon injury.

CB 2679d/ISU304, a highly potent next-generation coagulation Factor IX variant, has demonstrated the potential to normalize human Factor IX levels with a daily subcutaneous injection in preclinical studies. Catalyst's collaborator, ISU Abxis (KOSDAQ:086890), plans to initiate a Phase 1/2 proof-of-concept study with single and multiple subcutaneous injections in individuals with severe hemophilia B in the second quarter of 2017.

"We are very pleased with the progress we and our collaborator ISU Abxis have made in advancing this Factor IX candidate towards the clinic and we look forward to the initiation of a Phase 1/2 clinical trial next quarter," said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. "We believe that stopping bleeding is good, but preventing bleeding is better. CB 2679d/ISU304 has the properties required, including high potency, to allow for daily subcutaneous injection with the potential to achieve stable and normal Factor IX clotting levels."

Catalyst has a collaboration with ISU Abxis to advance the development of CB 2679d/ISU304 through a Phase 1/2 proof-of-concept study in individuals with severe hemophilia B. After Phase 1/2, ISU Abxis has an option for exclusive commercial rights in South Korea and a profit share on ex-South Korean commercialization. Catalyst retains full development and commercial rights for CB 2679d/ISU304 outside of South Korea.

About Factor IX
CB 2679d/ISU304 is a next-generation coagulation Factor IX variant that is IND-approved in South Korea. CB 2679d/ISU304 has exhibited enhanced procoagulant activity, improved efficacy in inhibiting blood loss, and prolonged duration of action in bleeding and non-bleeding preclinical models compared with other Factor IX products on the market. Catalyst believes that CB 2679d/ISU304 may allow for subcutaneous prophylactic treatment of individuals with hemophilia B.

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 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 a potent 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 IND-approved in Korea. 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 statements of historical facts, included in this press release regarding our strategy, the potential uses and benefits of CB 2679d/ISU304 and marzeptacog alfa (activated), and development plans for these product candidates 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 initiation two trials in 2017, the potential uses and benefits of subcutaneously dosed CB 2679d/ISU304 and marzeptacog alfa (activated), ISU Abxis' plans to initiate a Phase 1/2 proof-of-concept study, and the potential for CB 2679d/ISU304 to allow for subcutaneous prophylactic treatment of individuals with hemophilia B and to achieve stable and normal Factor IX clotting levels. Actual results or events could differ materially from the plans, 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 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 described in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and S-1 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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