Catalyst Biosciences and ISU Abxis Complete Dosing of First Patient Cohort in Hemophilia B Clinical Trial

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-- Phase 1/2 proof-of-concept study will evaluate Catalyst's next-generation Factor IX variant for subcutaneous prophylaxis --

SOUTH SAN FRANCISCO, Calif. and SEOUL, South Korea, June 14, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, and ISU Abxis Co Ltd. (KOSDAQ: 086890) a commercial-stage biopharmaceutical company and Catalyst's collaborator in the development of its Factor IX variant, today announced that ISU Abxis has completed dosing of the first of up to five patient cohorts in a Phase 1/2 proof-of-concept clinical trial in individuals with severe hemophilia B. The Companies plan to have top line data from the trial by the end of 2017.

The clinical trial will include single intravenous and subcutaneous dosing cohorts, followed by daily subcutaneous injections of CB 2679d/ISU304, Catalyst's highly potent next-generation coagulation Factor IX variant. Currently approved hemophilia B therapies require frequent intravenous infusions where adherence and convenient access to peripheral veins is difficult, often necessitating the use of a central venous access device with the associated risks of infection and thrombosis, and do not result in sustained normalization of FIX activity.

"We believe that individuals with hemophilia B would welcome a subcutaneous prophylaxis therapy that eliminates intravenous infusions required to manage or control spontaneous bleeding and provides the potential to provide normal FIX activity levels at all times," said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. "With the completion of dosing of the first cohort, we anticipate sharing top line data from the Phase 1/2 trial by year-end."

"Catalyst's approach to creating improved, next-generation, pro-coagulants is unique and, we believe, has the potential to lead to a promising therapeutic option for individuals with hemophilia B," said Seok Joo Lee, Chief Executive Officer of ISU Abxis. "We are pleased to be leading the Phase 1/2 clinical trial program on behalf of our collaboration, and that this first clinical trial of CB 2679d/ISU304 is taking place in South Korea."

In May 2017, the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending orphan medicinal product (orphan drug) designation for CB 2679d/ISU304 for the treatment of hemophilia B.

Catalyst has a collaboration with ISU Abxis to advance the development of CB 2679d/ISU304 in individuals with severe hemophilia B. After completing the Phase 1/2 trial, 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 the Clinical Trial
The Phase 1/2 proof-of-concept clinical trial in individuals with severe hemophilia B will include single intravenous and subcutaneous dosing cohorts, followed by daily subcutaneous injections of CB 2679d/ISU304, Catalyst's next-generation coagulation Factor IX variant. The study is an open label trial with the objective of studying the pharmacokinetics, subcutaneous bioavailability and steady-state FIX levels that result from daily dosing for six days of CB 2679d/ISU304. The trial is currently being conducted at three centers in South Korea. The trial is expected to enroll up to 17 individuals with hemophilia B and to be completed in the first quarter of 2018. The clinical objective of the trial is to achieve normal Factor IX activity trough levels.

About Factor IX
CB 2679d/ISU304 is a next-generation 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/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, the potential uses and benefits of CB 2679d/ISU304 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/ISU304 or the plans to share top line data from the Phase 1/2 study by the end of 2017, and the potential uses and benefits of subcutaneously dosed CB 2679d/ISU304. 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 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 filed with the SEC on March 8, 2017. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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