Key Milestone Reached in Catalyst's Subcutaneous Factor IX Program

April 11, 2017

-- Milestone payment received with completion of IND-enabling toxicology studies --

-- 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., April 11, 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 it has achieved a key milestone under its collaboration with ISU Abxis to advance the Factor IX program towards its first human clinical trial. Completion of the CB 2679d/ISU304 toxicology studies supported the recent Investigational New Drug (IND) approval by the Korean Ministry of Food and Drug Safety (MFDS) and triggered a milestone payment to Catalyst.

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. Currently approved therapies rely on frequent intravenous infusions where adherence is difficult and convenient access to peripheral veins is a problem, often requiring the use of central venous access devices with the associated risks of infection and thrombosis. 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.

"Individuals with severe hemophilia B will experience abnormal bleeding - not just after an injury, but spontaneously into potentially any organ, joints or muscles. Without preventative treatment or prophylaxis, these individuals may experience several spontaneous bleeding episodes per month," said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. "Our vision is to prevent bleeding with the stabilization and normalization of clotting levels using more convenient subcutaneous dosing."

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. Under the license agreement, the next potential milestone payment is for the first patient enrolled in the Phase 1/2 trial.

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, 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 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 initiation of a Phase 1/2 proof-of-concept study for CB 2679d/ISU304 in the second quarter of 2017, the potential uses and benefits of subcutaneously dosed CB 2679d/ISU304, and the timeline for the next potential milestone payment. 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 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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