Catalyst Biosciences Announces Positive Factor IX Clinical Data

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-- CB 2679d/ISU304 is approximately 22 times more potent than current hemophilia B therapy --

SOUTH SAN FRANCISCO, Calif., Sept. 06, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO), today announced positive clinical data from the first Cohort of its ongoing Phase 1/2 proof-of-concept clinical trial in individuals with severe hemophilia B.

Cohort 1 results (N = 3) demonstrate:

- An intravenous dose of CB 2679d is approximately 22 times more potent than an intravenous dose of BeneFIX® as measured by activity levels using a one-stage clotting assay; and
- The average time that CB 2679d stayed in the circulation was significantly longer at 34 hours compared with BeneFIX at 25 hours.

These potency results, which are consistent with the Company's earlier research, support that CB 2679d has the potency advantage needed to be delivered as a convenient subcutaneous prophylactic therapy to prevent spontaneous bleeding in individuals with Hemophilia B.

"We are excited that the higher potency and improved pharmacokinetics of CB 2679d have been demonstrated in this clinical trial. We believe that CB 2679d will have advantages over the currently approved intravenous prophylactic treatments that are known to have a prolonged period of low activity levels with increased risk of spontaneous bleeding," said Nassim Usman, Ph.D., Catalyst's President and Chief Executive Officer.

About the Ongoing Clinical Trial
The clinical trial is being conducted at three centers in South Korea by the Company's collaborator, ISU Abxis, which uses ISU304 as an alternate product name. The trial will, among other things, document the subcutaneous bioavailability and clotting ability of CB 2679d achieved with single intravenous and subcutaneous dosing cohorts, followed by daily subcutaneous injections of CB 2679d in the fifth cohort. Interim, top-line results of this open-label study are expected by the end of 2017 and complete trial results in early 2018.

About Factor IX
CB 2679d 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 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. 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 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 or 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 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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