Catalyst Biosciences Announces Acceleration of Phase 1/2 Trial of CB 2679d/ISU304 in Individuals with Hemophilia B

December 18, 2017

Korean Ministry of Food and Drug Safety Approves Omitting Cohort 4 and Dosing Cohort 5 with Six Daily Subcutaneous Doses of Next-Generation Coagulation Factor IX

Current lower doses are predicted to achieve normal Factor IX levels

SOUTH SAN FRANCISCO, Calif., Dec. 18, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO), today announces that the Korean Ministry of Food and Drug Safety (MFDS) has approved a protocol amendment to omit single dose Cohort 4 (300 IU/kg daily – "high dose") and move directly to multi-dose Cohort 5 at 150 IU/kg daily, in the ongoing Phase 1/2 multi-dose study of CB 2679d/ISU304, Catalyst's highly potent next-generation coagulation Factor IX (FIX) variant in individuals with severe hemophilia B.

"In approving this protocol amendment to accelerate our Phase 1/2 trial, the MFDS agrees that the high single dose of CB 2679d contemplated in Cohort 4 is not required, as current lower subcutaneous (SQ) doses are already predicted to achieve normal Factor IX levels after multi-dose administration," said Dr. Howard Levy, chief medical officer of Catalyst. "Data from Cohorts 1 through 3 demonstrated that the half-life of CB 2679d was almost five times greater than intravenous wild-type FIX, allowing for this favorable protocol amendment. We are currently enrolling patients in the final multi-dose cohort and, with the accelerated protocol, expect to have multi-dose data in Q1 2018."

Interim data from Cohorts 1 through 3 were presented at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition. The data showed that SQ delivery significantly increases the half-life of CB 2679d to 98.7 hours, equivalent to the half-life of extended-half-life intravenous agents. These data support the potential normalization of FIX activity in individuals with hemophilia B with daily or less-frequent SQ dosing.

About the FIX Phase 1/2 Trial
CB 2679d is designed as a best-in-class high potency recombinant Factor IX product. The Phase 1/2 clinical trial of CB 2679d in patients with severe hemophilia B 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 aims to measure the subcutaneous bioavailability and clotting ability of CB 2679d achieved after single intravenous and subcutaneous dosing in the first three cohorts, followed by daily subcutaneous injections of CB 2679d in the final cohort. Catalyst believes that CB 2679d may allow for subcutaneous prophylactic treatment of individuals with hemophilia B by achieving normal activity levels in blood. In June 2017, the European Commission and in September 2017, the U.S. Food and Drug Administration (FDA) granted orphan drug designations for CB 2679d. Complete trial results are expected in Q1 2018.

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 http://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, expected complete trial results by Q1 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 multiple subcutaneous dosing of CB 2679d may result in potential adverse effects, including the generation of neutralizing antibodies (inhibitors), 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 November 2, 2017. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

Contacts:
Investors:
Fletcher Payne, CFO
Catalyst Biosciences
1.650.871.0761

Media:
Josephine Belluardo, Ph.D.
LifeSci Public Relations

1.646.751.4361
jo@lifescipublicrelations.com

Catalyst Biosciences, Inc.