Catalyst Biosciences Announces Interim Phase 1/2 CB 2679d/ISU304 Results at the American Society of Hematology Conference

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Subcutaneous (SQ) delivery significantly increases half-life of CB 2679d to 98.7 hours

Data supports potential normalization of FIX activity with daily or less-frequent SQ dosing

SOUTH SAN FRANCISCO, Calif., Dec. 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 interim Phase 1/2 data on its subcutaneously administered, prophylactic Factor IX variant CB 2679d/ISU304 in an oral presentation at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition held on Dec. 9-12, 2017 in Atlanta. The data demonstrate that subcutaneous delivery of CB 2679d significantly increases the factor IX (FIX) activity half-life to 98.7 hours.

Dr. Howard Levy, chief medical officer of Catalyst, presented results from the first three cohorts of the Phase 1/2 trial of CB 2679d in patients with severe hemophilia B. During these first three cohorts, patients received single intravenous (IV) and subcutaneous (SQ) doses of CB 2679d. Results from cohort 1, which compared 75 IU/kg IV CB 2679d with 75 IU/kg IV BeneFIX, showed that IV CB 2679d is approximately 22 times more potent and has a significantly longer half-life (27 *vs* 21 hours, p = 0.0014) and mean residence time than BeneFIX (36 hours *vs* 25 hours, p = 0.00004). Cohorts 2 and 3 compared 75 IU/kg IV CB 2679d with 75 IU/kg and 150 IU/kg SQ CB 2679d respectively. These results showed that SQ delivery of CB 2679d had a bioavailability of 18.5% and significantly increases the FIX activity half-life to 98.7 hours *vs* 27.6 hours for a IV dose of 75 IU/kg, (p = 0.005). No serious adverse events were observed. The data to date support the potential of achieving normal FIX levels in individuals with hemophilia B with daily or less frequent subcutaneous dosing.

“The results from these first three cohorts demonstrate the promise of CB 2679d as a safe prophylactic treatment for patients with hemophilia B,” said Dr. Levy. “The significantly increased half-life of CB 2679d and bioavailability after subcutaneous dosing suggests that CB 2679d may provide superior prophylaxis capabilities compared with intravenous extended half-life agents, with the potential to normalize FIX levels. We eagerly await the results from daily subcutaneous doses of CB 2679d on Factor IX blood levels that are expected in early 2018.”

About the 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 four cohorts, followed by daily subcutaneous injections of CB 2679d in the fifth, and final, cohort. 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 early 2018.

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, the plans to disclose 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 later trials will not replicate the results from earlier trials or preclinical 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 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.

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