



Catalyst Biosciences Announces Korean Ministry of Food and Drug Safety Approves Addition of Sixth Cohort to the Phase 1/2 Trial of CB 2679d/ISU304 in Individuals with Hemophilia B

April 12, 2018

Initiation of Phase 2b Trial on Track for Q3 2018

SOUTH SAN FRANCISCO, Calif., April 12, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced that the Korean Ministry of Food and Drug Safety (MFDS) approved the addition of a sixth cohort to the Phase 1/2 trial of CB 2679d in individuals with severe hemophilia B following positive data from the multi-dose Cohort 5 that was disclosed on February 9.

Cohort 6 will enroll up to five patients. Each individual will receive a single intravenous loading dose of 75 IU/kg, followed by nine daily subcutaneous doses of 150 IU/kg CB 2679d. The loading dose will be administered 30 minutes before the first subcutaneous dose. The study will be completed in South Korea in coordination with the Company's collaborator ISU Abxis.

"The addition of this sixth cohort will allow us to build on the progressive increase in Factor IX activity levels, from severe to mild hemophilia, that we observed after six daily subcutaneous doses in Cohort 5 of this Phase 1/2 trial," said Nassim Usman, Ph.D., chief executive officer of Catalyst. "The Cohort 6 design will also allow us to evaluate the benefits of a single IV loading dose of CB 2679d. Interim results from this sixth cohort are expected in Q3 2018 with additional data in Q4 2018. Data from this cohort will inform the design of future trials, including the upcoming Phase 2b trial, planned to begin in Q3 2018."

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 measures the potency, subcutaneous bioavailability, half-life and clotting ability of CB 2679d achieved after single intravenous and subcutaneous dosing in the first three cohorts, and daily subcutaneous injections of CB 2679d with and without an intravenous loading dose in the fifth cohort and sixth cohorts, respectively. Catalyst believes that CB 2679d may provide a subcutaneous prophylactic treatment for individuals with hemophilia B by achieving high-mild hemophilia FIX activity levels in blood. CB 2679d was awarded orphan drug designations by the European Commission in June 2017 and by the U.S. Food and Drug Administration (FDA) in September 2017.

About Catalyst

Catalyst is a clinical-stage biopharmaceutical company 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 fact, 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, the potential for subcutaneous dosing of CB2679d to maintain clotting activity in the high-mild hemophilia range, plans for the commencement of a Phase 2b clinical trial of CB 2679d, and the anticipated results of Cohort 6 are forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements as a result of various important factors, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that Cohort 6 will not replicate the results from earlier human trials (including Cohort 5) or from prior animal studies, that potential adverse effects may arise from the testing or use of the Company's products, including the generation of antibodies, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 19, 2018, along with our other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

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