Catalyst Biosciences Provides Update on CB 2679d/ISU304 Factor IX Clinical Program in Hemophilia B

June 18, 2018

Conference call and webcast to be held today, June 18, 2018 at 8:30 a.m. EDT

SOUTH SAN FRANCISCO, Calif., June 18, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today provided an update on the ongoing Phase 1/2 trial investigating its next generation Factor IX (FIX) candidate CB 2679d/ISU304 for the treatment of severe hemophilia B.

In April 2018, the Phase 1/2 trial, which is being conducted by Catalyst's collaborator ISU Abxis in South Korea, was amended to add a Cohort 6. In this cohort, each patient receives a single loading dose of 75 IU/kg CB 2679d/ISU304 given intravenously, followed by nine daily subcutaneous doses of 150 IU/kg CB 2679d/ISU304, starting half an hour after the intravenous dose. To date, Cohort 6 has enrolled two patients out of a planned three to five and has shown promising efficacy in both. During the treatment period, FIX activity levels always remained above 20% after the IV loading dose in both patients. The first patient then had a progressive increase in trough FIX activity level to 34% and the second patient to a trough activity level of 31%. Patients with FIX levels between 5% and 40% are considered to have mild hemophilia, according to the World Federation of Hemophilia.

Subsequent blood samples showed the presence of a transient neutralizing antibody in one patient and a neutralizing antibody in the second. Importantly from a safety perspective, the antibodies do not bind to wildtype FIX allowing both patients to successfully resume treatment with their prescribed intravenous FIX prophylaxis therapies; the patients have not experienced any bleeds or other safety issues and are being closely monitored. Prior to Cohort 6, no CB 2679d neutralizing antibodies had been detected in any of the patients treated with CB 2679d/ISU304, including both patients in Cohort 6 who had also participated in Cohort 5. Catalyst is conducting an analysis to assess the cause and impact of the antibody observations prior to dosing any further subjects in Cohort 6.

"The most recent data from the ongoing Phase 1/2 trial have demonstrated clinical proof of concept for subcutaneous dosing of a potent FIX as a treatment for hemophilia B. Patients in Cohort 6 of the trial were able to maintain Factor IX levels over 30% which is at the upper end of mild hemophilia and higher than currently approved extended half-life (EHL) intravenous Factor IXs," said Nassim Usman, Ph.D., chief executive officer of Catalyst. "Our next steps will be to carefully identify the cause and nature of the antibodies and provide further updates once we have the results of our analysis."

Catalyst's Phase 2 study of daily subcutaneous injections of its next generation Factor VIIa marzeptacog alfa (activated) for the treatment of hemophilia A or B with inhibitors and Catalyst's preclinical dry age-related macular degeneration (dry AMD) programs are continuing to progress as planned. Catalyst's cash balance as of March 31, 2018 was approximately $143 million.

About the FIX Phase 1/2 Trial
CB 2679d/ISU304 was designed as a best-in-class high potency recombinant Factor IX (FIX) product. Catalyst believes that CB 2679d/ISU304 may provide a subcutaneous prophylactic treatment for individuals with hemophilia B by achieving high-mild hemophilia FIX activity levels in blood. The Phase 1/2 clinical trial of CB 2679d/ISU304 in patients with severe hemophilia B is being conducted at three centers in South Korea by Catalyst's collaborator, ISU Abxis, which uses ISU304 as an alternate product name. The trial is investigating the potency, subcutaneous bioavailability, half-life and clotting ability of CB 2679d/ISU304 achieved after single intravenous and subcutaneous dosing in the first three Cohorts, and daily subcutaneous injections of CB 2679d/ISU304 without and with an intravenous loading dose in the 5th and 6th cohorts, respectively. CB 2679d/ISU304 was awarded orphan drug designations by both the European Commission and U.S. Food and Drug Administration (FDA) in 2017.

Conference Call Details
The management team will host a conference call for investors today, Monday June 18, 2018, at 8:30 a.m. EDT to discuss the FIX clinical program update. Conference call, webcast and post-conference call replay details are as follows:

Domestic: +1.888.394.8218
International: +1.323.701.0225
Conference ID: 8295220
Webcast: http://public.viavid.com/index.php?id=130156

Replay will be available two hours after completion of the call through July 2, 2018:
Domestic: +1.844.512.2921
International: +1.412.317.6671
Replay ID: 8295220

The call will also be archived on the Company's website for 30 days at www.catalystbiosciences.com.

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

candidate and other candidates 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, the lack of binding of CB 2679d neutralizing antibodies with wildtype FIX and plans to analyze the cause of neutralizing antibodies in patients treated with CB 2679d. 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 the development program for CB 2679d may be significantly delayed or suspended or 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 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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