



Catalyst Biosciences Announces Positive Top-Line Data from Phase 1/2 Study of Subcutaneous CB 2679d/ISU304 in Individuals with Hemophilia B

February 9, 2018

All individuals with severe hemophilia improved to mild hemophilia activity levels after only six daily doses with a continuous linear increase in Factor IX clotting activity

These results suggest that long-term dosing of SQ CB 2679d has the potential to maintain stable clotting activity in the high-mild hemophilia to normal range

Conference call and webcast to be held today, February 9, 2018, at 8:30 a.m. EST

SOUTH SAN FRANCISCO, Calif., Feb. 09, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced top-line data from its Phase 1/2 study of subcutaneous (SQ) prophylactic candidate CB 2679d/ISU304 being developed for the treatment of hemophilia B in an oral presentation at the 11th Annual Congress of The European Association for Haemophilia and Allied Disorders (EAHAD) in Madrid. Results from the trial showed a continuous linear increase in Factor IX (FIX) activity levels following daily dosing of CB 2679d for six days.

"These exciting results demonstrate for the first time the feasibility of a subcutaneous FIX injection to provide meaningful protection from bleeding, even after only six doses," said Dr. John Pasi, professor of haemostasis and thrombosis at Barts and The London School of Medicine and Dentistry. "As a result, this treatment option has the potential to normalize coagulation activity and dramatically improve the quality of life of individuals affected by hemophilia B."

Dr. Howard Levy, chief medical officer of Catalyst, presented results from the fifth cohort of the Phase 1/2 trial of CB 2679d in patients with severe hemophilia B. After six days of once-daily SQ dosing, CB 2679d increased FIX activity levels in 5 patients who were each dosed daily with 140 IU/kg SQ, from very low levels after washout of prior therapy to a median FIX activity level of 16% (range 11.5-18%), that is well into the mild hemophilia range (5-40%), and is higher than a level required to prevent hemarthrosis. The observed increase in FIX activity levels after the daily dosing was linear, indicating that continued SQ dosing may achieve high-mild hemophilia or even normal FIX clotting activity. Terminal SQ half-life was 63.2 hours (interquartile range 60.2-64 hours) with the result that activity levels were still 4-6.4%, 5 days after the last dose. No inhibitors to CB 2679d or FIX were induced to date. One subject had moderate adverse events of pain, erythema and redness after the first 2 injections and mild rating after subsequent injections. Other subjects in cohort 5 reported some of these adverse events, mainly with initial injections. Two subjects had bruising after injection when FIX activity levels were low that did not occur with subsequent injections as FIX activity levels rose. Presentation materials can be accessed [here](#).

Dr. Levy remarked, "Existing IV therapies have FIX trough levels that can drop as low as 1-3% before repeat dosing. Daily subcutaneous dosing of CB 2679d has the potential to minimize the variability in FIX activity levels observed between IV doses and maintain individuals in the mild or even normal hemophilia range. This study demonstrates that, even after just six days of treatment, CB 2679d compares favorably to currently approved therapies for hemophilia B, all of which are infused IV."

Conference Call and Webcast

The management team will host a conference call with slides for investors today, Friday Feb. 9, 2018, at 8:30 a.m. EST to discuss the data and answer questions. Conference call, webcast and post-conference call replay details are as follows:

Domestic: +1.800.239.9838

International: +1.323.794.2551

Conference ID: 8902500

Webcast: <http://public.viavid.com/index.php?id=128119>

Replay will be available two hours after completion of the call through Feb. 23:

Domestic: +1.844.512.2921

International: +1.412.317.6671

Replay ID: 8902500

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

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 was conducted at three centers in South Korea by the Company's collaborator, ISU Abxis, which uses ISU304 as an alternate product name. The trial measured the potency, subcutaneous bioavailability, half-life 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 fifth cohort. Catalyst believes that CB 2679d may provide a subcutaneous prophylactic treatment for individuals with hemophilia B by achieving high-mild hemophilia or normal clotting 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. Future studies with CB 2679d are planned, with the goal of evaluating greater duration of daily dosing at lower dose and less frequent dosing.

About Hemophilia

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. The severity of the disease is defined according to the percentage of normal factor activity in blood (50-150%). According to the definitions of the World Federation of Hemophilia, patients with severe disease have factor levels <1%, those with moderate disease have factor levels of 1-5% and those with mild disease have factor levels of 5%-40%. According to the World Federation of Hemophilia, individuals with severe hemophilia bleed spontaneously and frequently, as often as one to two times per week, those with moderate hemophilia bleed about once per month but rarely spontaneously, and those with mild hemophilia bleed rarely and some may never have a bleeding problem unless they have surgery or a trauma.

About Catalyst Biosciences

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 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, the potential for subcutaneous dosing of CB2679d to maintain clotting activity in the high-mild hemophilia to normal range. 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 subsequent clinical trials will not replicate the results from initial clinical studies with small numbers of patients, 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, Inc.
1.650.871.0761
investors@catbio.com

Media:

Josephine Belluardo, Ph.D.
LifeSci Public Relations
1.646.751.4361
jo@lifescipublicrelations.com



Catalyst Biosciences, Inc.