Catalyst Biosciences Announces Achievement of Stable Normal Factor IX Blood Levels in a Preclinical Subcutaneous Dosing Model

June 26, 2017

-- Data support ongoing clinical trial in individuals with hemophilia B --

-- Data to be presented at ISTH oral session Future Biotherapeutics for Hemophilia A and B --

SOUTH SAN FRANCISCO, Calif., June 26, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (Nasdaq:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced positive preclinical results of CB 2679d/ISU304, its next-generation coagulation Factor IX, in a well-validated preclinical model of hemophilia B. The results demonstrate the attractive pharmacokinetic and pharmacodynamic profile of CB 2679d based on bioavailability, potency, time to maximal concentration, and half-life.

The Company's Factor IX preclinical program, including the results being presented at the International Society on Thrombosis and Haemostasis (ISTH) Meeting in July 2017, supported the initiation of an ongoing Phase 1/2 proof-of-concept clinical trial evaluating CB 2679d for subcutaneous prophylaxis.

At the meeting, the Company will also have a Factor VIIa Poster Presentation which supports the initiation of a Phase 2/3 clinical trial to evaluate subcutaneous dosing of marzeptacog alfa (activated); the Phase 2 portion of the trial is expected to commence by the end of 2017.

"Catalyst's CB 2679d corrected severe hemophilia to normal coagulation activity in hemophilia B dogs after only six daily subcutaneous doses," said Howard Levy, M.B.B.Ch., Ph.D., M.M.M., Catalyst's Chief Medical Officer. "Given the potency and pharmacokinetic profile of CB 2679d observed in our preclinical studies, we are looking forward to open-label results from the ongoing Phase 1/2 subcutaneous dosing study in individuals with hemophilia B, as well as daily dosing results, towards the end of this year."

Oral Factor IX Presentation
Pharmacokinetics and Pharmacodynamics of Daily Subcutaneously Administered CB 2679d/ISU304 In Hemophilia B Dogs (abstract #OC 10.3)
Howard Levy, Timothy Nichols, Elizabeth Merricks, Robin Raymer, and Andrew Hetherington (Oral Communications Session: Future Biotherapeutics for Hemophilia A and B. Monday, July 10, 2017 at 10:00 am CEST)
The authors tested daily subcutaneous (SQ) doses of CB 2679d/ISU304 in hemophilia B dogs for six days. Factor IX antigen and activity were measured at various time points. The results are summarized as follows:

- CB 2679d/ISU304 corrected severe hemophilia to normal in hemophilia B dogs, after six daily subcutaneous doses
- Daily SQ dosing of CB 2679d after six doses had peak Factor IX activity levels of 60 and 53 percent at 126 hours
- Trough activity levels 24 hours after six daily doses were 56 and 40 percent respectively
- The progressive increase in Factor IX activity levels after daily SQ dosing of CB 2679d supported the initiation of the ongoing Phase 1/2 proof-of-concept subcutaneous dosing study in individuals with hemophilia B with the target of achieving normal Factor IX activity trough levels
- There were no emergent clinical adverse events or lab abnormalities recorded

Factor VIIa Poster Presentation
Pharmacokinetics and Pharmacodynamics of Subcutaneously Administered Marzeptacog Alfa (Activated) in Hemophilia B Mice (abstract #PB 1119)
Howard Levy, Nassim Usman, and Andrew Hetherington (Tuesday, July 11, 2017 from 12:00-13:15pm CEST)
The authors tested subcutaneous doses of marzeptacog alfa (activated) in hemophilia B mice. Factor VIIa antigen and activity were measured at various time points. The results are summarized as follows:

- Daily subcutaneous dosing (0.5 mg/kg) had trough levels of marzeptacog alfa (activated) 29.9 to 76.9 (mean 43.4) ng/mL and increased two hours after administration to 267.4 to 362 (mean 323.9) ng/mL
- Daily subcutaneous dosing (1 mg/kg) achieved trough levels of marzeptacog alfa (activated) 50 to 80.9 (mean 63.7) ng/mL and increased two hours after administration to 230.8 to729.5 (mean 471.9) ng/mL
- Increased potency of marzeptacog alfa (activated), blood drug levels and reduction in activated partial thromboplastin time (aPTT) achieved, support the initiation of a Phase 2/3 subcutaneous dosing study in individuals with hemophilia A and B with inhibitors, with a target of achieving normal coagulation pharmacodynamics

The abstracts can be found on the ISTH website. A PDF of the Factor IX oral presentation slides and the Factor VIIa poster will be available on the Company's website on Monday, July 10 and Tuesday, July 11, respectively.

About Factor IX
CB 2679d/ISU304 is a next-generation coagulation Factor IX variant that is being evaluated in a Phase 1/2 proof-of-concept clinical trial in South Korea. Catalyst believes that CB 2679d/ISU304 may allow for subcutaneous prophylactic treatment of individuals with hemophilia B. Learn more about Factor IX.

About Factor VIIa

Marzeptacog alfa (activated) is a high potency next-generation Factor VIIa that is initially being developed for the subcutaneous prophylactic treatment of individuals with severe hemophilia A and B with inhibitors. An inhibitor is a potential complication for individuals with hemophilia receiving factor replacement therapy resulting from the production of antibodies against the replacement factor. Learn more about Factor VIIa.

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.

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, 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/ISU304 and marzeptacog alpha (activated) and development plans for these product candidates are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to preclinical models showing efficacy or therapeutically relevant blood levels of these product candidates following subcutaneous dosing, Catalyst's clinical trial timelines, including the initiation of efficacy Phase 2/3 study for marzeptacog alfa (activated) in 2017, the anticipated completion of a Phase 1/2 proof-of-concept study for CB 2679d/ISU304 or the plans to have results from this study by the end of 2017, and the potential uses and benefits of subcutaneously dosed marzeptacog alfa (activated) or CB 2679d/ISU304. 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 the human trials will not replicate the results from animal studies, that trials and enrollment may be delayed and may not have satisfactory outcomes, 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 Annual Report on Form 10-K filed with the SEC on March 8, 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.
650.871.0761
investors@catbio.com

Media:
Denise Powell
Red House Consulting, LLC
510.703.9491
denise@redhousecomms.com

Catalyst Biosciences, Inc.