Catalyst Biosciences Announces Positive Preclinical Data with Subcutaneous Dosing of Coagulation Factor IX at ASH Annual Meeting

November 14, 2016

-- CB 2679d/ISU304 Demonstrates Beneficial Effect in Hemophilia B Murine Models Using Subcutaneous Dosing --

-- Subcutaneous Phase 1/2 Proof-of-Concept Clinical Trial of High-Potency Factor IX CB 2679d/ISU304 in Individuals with Hemophilia B to Commence in the First Quarter of 2017 --

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2016 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced positive results from a preclinical study of CB 2679d/ISU304 in well-validated models of hemophilia B. The study highlighted the attractive pharmacokinetic profile of CB 2679d/ISU304 based on bioavailability, potency, time to maximal concentration, and half-life, which resulted in the ability to dose CB 2679d/ISU304 subcutaneously while also achieving steady-state levels of procoagulant activity that moved hemophilia B mice from the severe range to the mild range.

Catalyst is focused on the prevention of spontaneous bleeding in hemophilia through the development of clotting factors that may be injected subcutaneously. Hemophilia B is a chronic disease caused by a genetic deficiency in coagulation Factor IX. The current approach to treating acute bleeding episodes in individuals with hemophilia B includes the use of recombinant human Factor IX, which has low potency and is therefore not appropriate for subcutaneous prophylactic treatment.

“These results support our earlier preclinical findings that CB 2679d/ISU304 has significantly higher potency compared with other Factor IX products that cannot be practically dosed by subcutaneous injection to achieve satisfactory levels of drug. If these preclinical results can be duplicated in patients, not only would CB 2679d/ISU304 provide greater convenience, but could potentially provide better efficacy since CB 2679d/ISU304 may result in steady state FIX activity levels consistent with normal coagulation,” said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. “Based on the totality of our preclinical data, we and our partner, ISU Abxis, are preparing to initiate a Phase 1/2 proof-of-concept clinical trial in individuals with hemophilia B in the first quarter of 2017. We believe that CB 2679d/ISU304 may ultimately provide individuals with hemophilia B prophylaxis by subcutaneous injection.”

The results, being presented in a poster session at the American Society of Hematology (ASH) 58th Annual Meeting in San Diego, Calif. from December 3 to 6, 2016, are summarized below:

Pharmacokinetics of Subcutaneously Administered CB 2679d/ISU304 in Wild-Type and Hemophilia B Mice (Poster abstract #1389, Session: 321 Blood Coagulation and Fibrinolytic Factors)
Seung-Beom Hong, PhD, Howard Levy, MBBChir, PhD, Jae Yong Jung, MS, Minkyung Park, AS, A Rim Seo, AS, So Hyeon Seo, MS and Ed Madison, PhD

The authors tested subcutaneous doses of CB 2679d/ISU304 in both hemophilia B and wild-type mice. The wild-type mice also received subcutaneous doses of BeneFIX. Factor IX antigen and activity were measured at various time points. The following conclusions were made:

- There was a dose-dependent increase in plasma Factor IX antigen with subcutaneous CB 2679d/ISU304;
- The pharmacokinetic profile of CB 2679d/ISU304 was similar to BeneFIX when dosed using the same mass, however, CB 2679d/ISU304 has approximately 17-times greater potency;
- Due to the high specific activity of CB 2679d/ISU304, a subcutaneous dose of CB 2679d/ISU304 yields much higher Factor IX activities in mouse plasma compared with the same mass dose of BeneFIX; and
- Daily subcutaneous dosing of CB 2679d/ISU304 demonstrated the effects of the bioavailability, potency, time to maximal concentration, and half-life by reaching a steady-state activity after three days, sufficient to correct severe hemophilia to mild hemophilia in hemophilia B mice.

For more information about Catalyst Biosciences, including a recent corporate update, please see the webcast replay of an expert panel meeting titled *Advances in Hemophilia Treatment* that occurred on November 10, 2016. Advances in Hemophilia: Catalyst Biosciences Webcast

About Factor IX
CB 2679d/ISU304 is a next-generation coagulation Factor IX variant that is in advanced preclinical development. CB 2679d/ISU304 has exhibited enhanced procoagulant activity, improved efficacy in inhibiting blood loss, and prolonged duration of action in bleeding and non-bleeding preclinical models compared to other Factor IX products on the market and in development. Based on these findings, Catalyst believes that CB 2679d/ISU304 may represent a novel, high-potency FIX variant. Catalyst has a collaboration with ISU Abxis to advance the development of CB 2679d/ISU304 through a Phase 1/2 proof-of-concept study in individuals with hemophilia B. After Phase 1, ISU Abxis retains exclusive commercial rights in South Korea while Catalyst retains full development and commercial rights for CB 2679d/ISU304 outside of South Korea.

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. There are two major types of hemophilia, A and B, that are caused by alterations in Factor VIII or Factor IX genes, respectively, with a corresponding deficiency in the affected proteins. The prevalence of hemophilia A and B in the United States is estimated to be

around 20,000 people, with more than 400,000 cases worldwide. Individuals with hemophilia suffer from spontaneous bleeding episodes as well as substantially prolonged bleeding times upon injury. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in permanent, disabling joint damage and can become life threatening. Treatment usually involves management of acute bleeding episodes or prophylaxis through factor replacement therapy by infusion of patients' missing Factor VIII or IX. With the frequent infusion schedule of current therapies, adherence is difficult. In addition, convenient access to peripheral veins is often a problem, and many children require use of central venous access devices, with the concomitant risks of infection and thrombosis.

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. Catalyst's most advanced program is an improved next-generation coagulation Factor VIIa variant, marzeptacog alfa (activated), that has successfully completed an intravenous Phase 1 clinical trial in individuals with severe hemophilia A or B. Catalyst is also developing a next-generation Factor IX variant, CB 2679d/ISU304, that is in advanced preclinical development. For more information, please visit www.catbio.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, future operations, and plans 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 initiation of a Phase 1/2 clinical trial for Factor IX CB 2679d/ISU304 in the first quarter of 2017 and the potential uses and benefits of subcutaneously dosed CB 2679d/ISU304. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the 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 studies may be delayed and may not have satisfactory outcomes, that human trials will not replicate the results from animal 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 that affect our ability to successfully develop and commercialize our product candidates described in the "Risk Factors" section of the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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