Catalyst Biosciences Announces Positive Preclinical Data of Subcutaneously Dosed Coagulation Factors VIIa and IX at EAHAD Annual Congress

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- Next-Generation Coagulation Factors Demonstrate Blood Levels After Subcutaneous Dosing Sufficient to Support Initiation of Clinical Studies in Individuals with Hemophilia B -

- Marzeptacog Alfa (Activated) Factor VIIa Efficacy Trial to Start in 2017; CB 2679d/ISU304 Factor IX Trial to Start in the Second Quarter of 2017 -

SOUTH SAN FRANCISCO, Calif., Feb. 01, 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 in well-validated models of hemophilia A and B with marzeptacog alfa (activated), a next-generation Factor VIIa, and CB 2679d/ISU304, a next-generation coagulation Factor IX. The results highlight the attractive pharmacodynamics and pharmacokinetic profiles of both coagulation factors based on bioavailability, potency, time to maximal concentration, and half-life that should allow for subcutaneous (SQ) dosing in individuals with hemophilia.

Catalyst plans to initiate a SQ efficacy trial of marzeptacog alfa (activated) in individuals with hemophilia B in 2017. In addition, Catalyst and its collaboration partner, ISU Abxis, plan to initiate a Phase 1/2 proof-of-concept IV/SQ clinical trial of CB 2679d/ISU304 in individuals with hemophilia B in the second quarter of 2017.

“These results demonstrate that CB 2679d/ISU304 has significantly higher potency compared with other Factor IX products and has the potential to be dosed by SQ injection and achieve stable normal activity levels - an attribute shared by no other Factor IX product on the market or in clinical development,” said Nassim Usman, Ph.D., President and Chief Executive Officer of Catalyst. “In addition, the marzeptacog alfa (activated) SQ preclinical results, daily SQ dosing achieved steady-state levels of Factor VIIa sufficient to correct coagulation abnormalities. We anticipate initiating a SQ efficacy trial of our next-generation Factor VIIa in individuals with hemophilia B with inhibitors in 2017.”

The results, being presented in poster sessions at the European Association of Haemophilia and Allied Disorders (EAHAD) 10th Annual Congress in Paris, France from February 1 to 3, 2017, are summarized below:

Pharmacokinetics and Pharmacodynamics Of Daily Subcutaneously Administered Marzeptacog Alfa (Activated) In Hemophilia Dogs (Poster abstract #P076)
Howard Levy, Timothy Nichols, Martin Lee, Elizabeth Merricks, Robin Raymer, and Andrew Hetherington.

The authors tested subcutaneous doses of marzeptacog alfa (activated) in hemophilia A dogs. The following conclusions were made:

- Bioavailability of subcutaneous injection was 44% and half-life was 50-136 hours;
- Daily subcutaneous dosing achieved steady-state levels of coagulation factor sufficient to correct the coagulation abnormality when compared with published data in hemophilic dogs that received FVIIa gene therapy and had no spontaneous bleeding for more than one year; and
- The increased potency of marzeptacog alfa (activated) and pharmacokinetic results support the initiation of a subcutaneous dosing efficacy study in individuals with hemophilia B with inhibitors.

Pharmacokinetics of Subcutaneously Administered CB 2679D/ISU304 In Minipig Compared with Benefix (Poster abstract #P074)
Seung-Beom Hong, Howard Levy, Jae Yong Jung, Minkyung Park, A Rim Seo, and June Young Park.

The authors administered subcutaneous doses of CB 2679d/ISU304 or BeneFIX to normal minipigs. Factor IX antigen and activity were measured at various time points. The following conclusions were made:

- CB 2679d/ISU304 has approximately 17-times greater potency than BeneFIX and therefore can achieve higher activity at an equal mass dosing level;
- Daily subcutaneous dosing of CB 2679d/ISU304 demonstrated the effects of the bioavailability, time to maximal concentration, and half-life by reaching a steady-state activity sufficient to correct severe hemophilia to normal, after four days of dosing;
- There was a dose-dependent increase in plasma Factor IX antigen with subcutaneous injection of CB 2679d/ISU304; and
- The increased potency of CB 2679d/ISU304 and pharmacokinetic results support the initiation of a Phase 1/2 subcutaneous dosing study in individuals with hemophilia B.

Pharmacokinetics and Pharmacodynamics of Daily Subcutaneously Administered CB 2679D/ISU304 In Hemophilia B Dogs (Poster abstract #P075)
Howard Levy, Timothy Nichols, Elizabeth Merricks, Robin Raymer, and Andrew Hetherington.

The authors tested subcutaneous doses of CB 2679d/ISU304 in hemophilia B dogs. Factor IX antigen and activity were measured at various time points. The following conclusions were made:

- Daily subcutaneous dosing of CB 2679d/ISU304 corrected severe hemophilia to normal in hemophilia B dogs, after 4 days of dosing;
- There was a progressive increase in plasma Factor IX antigen with daily subcutaneous injection of CB 2679d/ISU304; bioavailability of CB 2679d/ISU304 was 10.3% in Hemophilia B dogs; and
- The increased potency and pharmacokinetics of CB 2679d/ISU304 supports the initiation of the Phase 1/2 subcutaneous dosing study in individuals with hemophilia B with the objective of achieving stable normal Factor IX activity.

Posters are available for viewing and download from the Company's website in the Events section under Investors.

About Factor VIIa
Marzeptacog alfa (activated) is a next-generation Factor VIIa that successfully completed an intravenous Phase 1 clinical trial in severe hemophilia A and B with and without inhibitors. Marzeptacog alfa (activated) is being developed for the prophylactic treatment of severe hemophilia patients with inhibitors. Marzeptacog alfa (activated) was designed to combine higher clot-generating activity at the site of bleeding and improved duration of action.

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. Catalyst believes that CB 2679d/ISU304 may allow for subcutaneous prophylactic treatment of individuals with hemophilia B. 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 a potent 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 second quarter of 2017 and an efficacy trial of marzeptacog alfa (activated) in 2017, and the potential uses and benefits of subcutaneously dosed CB 2679d/ISU304 and marzeptacog alfa (activated). 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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