Catalyst Biosciences Announces Preclinical Proof-of-Concept Data of Gene Therapy Candidate CB 2679d-GT for the Treatment of Hemophilia B

February 6, 2019

Results show a four-fold reduction in bleeding time for CB 2679d-GT and a three-fold improvement in clotting activity when compared with an AAV-encoding Padua vector

Data presented at the 12th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD)

SOUTH SAN FRANCISCO, Calif., Feb. 06, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications presented preclinical proof-of-concept data of CB 2679d-GT Factor IX gene therapy in hemophilia B mice. The adeno-associated virus (AAV)-based CB 2679d Factor IX gene therapy candidate demonstrated superior results when compared with an AAV-encoded Padua vector in both reduction in bleeding times (four-fold reduction) and clotting activity (three-fold improvement). The data were presented in a poster at the 12th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) held Feb. 6-8, 2019 in Prague.

"These results are encouraging and demonstrate preclinical proof-of-concept for CB 2679d-GT, a gene therapy candidate encoding our engineered Factor IX as a potential new treatment for hemophilia B," said Nassim Usman, Ph.D., chief executive officer of Catalyst. "The data indicate that CB 2679d-GT achieves a more rapid and robust hemostatic correction of bleeding in hemophilia B mice with a significantly improved clotting activity and four-fold reduction of bleeding time when compared with an AAV-encoding FIX-R338L Padua. We remain committed to advancing dalcinonacog alfa (DalcA – subcutaneous recombinant CB 2679d) into a Phase 2b study this quarter and believe that CB 2679d-GT could be an important pipeline product that may provide additional treatment options for patients during their lifetime of therapy."

The 20-week preclinical study compared the activity of CB 2679d-GT with that of an AAV-encoding FIX-R338L Padua (FIX-Padua) in hemophilia B mice. Treatment with both CB 2679d-GT and FIX-Padua showed a reduced clotting time within the first week that remained stable up to the 20-week study endpoint. CB 2679d-GT demonstrated a statistically significant, three-fold improvement in clotting activity ($p < 0.04$), compared with FIX-Padua. Furthermore, when evaluated at 20 weeks, there was a four-fold reduction in bleeding time after treatment with CB 2679d-GT compared to FIX-Padua at both the $5x10^9$ vg/mouse ($p < 0.01$) and the $1x10^{10}$ vg/mouse ($p < 0.01$) dose levels. These results suggest that CB 2679d-GT exhibits a superior hemostatic potency when compared with FIX-Padua.

A copy of the poster can be accessed on the Events and Presentations section of the Catalyst website.

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 (including, but not limited to, statements about the potential for CB 2679d-GT to provide gene therapy treatment for hemophilia and plans to commence a Phase 2b study this quarter) are forward-looking statements. 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 the Company 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 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 that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 filed with the Securities and Exchange Commission on November 1, 2018, and with 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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