Catalyst Biosciences Announces Manufacturing Agreement with AGC Biologics for Subcutaneous Factor IX Product CB 2679d

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Catalyst plans to initiate a Phase 2b study of CB 2679d in Q3 2018

SOUTH SAN FRANCISCO, Calif., Feb. 26, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced that they have entered into a manufacturing agreement with AGC Biologics, a global leader in clinical and commercial manufacturing of therapeutic proteins, for the process transfer and commercial scale cGMP manufacturing of CB 2679d, Catalyst's highly potent next-generation coagulation Factor IX (FIX) variant being developed for the treatment of severe hemophilia B.

"AGC Biologics is a world-renowned company with deep expertise in recombinant biologics manufacturing and has successfully worked with Catalyst on our commercial scale FVIIa marzeptacog alfa program," said Andrew Hetherington, senior vice president of technical operations at Catalyst. "We are confident that their manufacturing expertise will allow us to continue our development and advancement of CB 2679d through the clinic in a timely manner. We plan to initiate a Phase 2b study of CB 2679d in individuals with severe hemophilia B in the third quarter of 2018."

AGC Biologics was formed from a merger of Asahi Glass Company (AGC) Bioscience, Biomeva GmbH and CMC Biologics. Catalyst had previously entered into a manufacturing agreement with CMC Biologics for its next-generation Factor VIIa product marzeptacog alfa (activated) in May 2016, making this the second manufacturing agreement Catalyst has with the company.

About CB 2679d
CB 2679d is designed as a best-in-class high potency recombinant Factor IX product. Phase 1/2 results from a study of CB 2679d in individuals with severe hemophilia B demonstrated that CB 2679d may provide a subcutaneous prophylactic treatment by achieving high-mild hemophilia 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.

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, plans for the continued clinical development of CB 2679d and commencement of a Phase 2b study in the third quarter of 2018, plans to transfer the manufacturing process of CB2679d to AGC Biologics and develop commercial scale manufacturing capabilities, and the potential for subcutaneous dosing of CB2679d to maintain clotting activity in the high-mild hemophilia 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 of delays or complications in the transfer of the manufacturing process to AGC Biologics, the risk that the commencement of the Phase 2b clinical trial of CB 2679d could be delayed as a result of manufacturing delays or other factors, and 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.

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