

Catalyst Biosciences Announces Oral and Poster Presentations at the World Federation of Hemophilia Virtual Summit 2020

June 8, 2020

SOUTH SAN FRANCISCO, Calif., June 08, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced oral and poster presentations at the upcoming World Foundation of Hemophilia Virtual Summit, taking place from June 14-19, 2020.

The poster abstract is now available online and can be accessed at https://www.wfh.org/virtual-summit/home.

Presentation details:

Phase 2b Trial to evaluate the safety and factor IX levels of a daily subcutaneous prophylaxis treatment

Poster Title: regimen of dalcinonacog alfa in hemophilia B

Presenting Author:

Howard Levy, M.B.B.Ch., Ph.D., M.M.M., chief medical officer, Catalyst Biosciences

Date: June 14-19, 2020

Combination of a Novel Chimeric AAV Capsid and Potency Enhanced FIX Variant for Hemophilia B Gene

Oral Title: Therapy

Presenting

Author: Grant E. Blouse, Ph.D., M.S., senior vice president of translational research, Catalyst Biosciences

Date/Time: June 19, 2020, 11:45 A.M. EDT

The open-label Phase 2b study of dalcinonacog alfa (DalcA), a next-generation subcutaneously (SQ) administered Factor IX (FIX) for the treatment of hemophilia B was designed to evaluate daily SQ dosing and the ability to maintain protective steady state FIX levels above 12% in six individuals with severe hemophilia B. Each subject received a single intravenous dose, followed by daily SQ doses of DalcA for 28 days whereby the pharmacokinetics, pharmacodynamics, safety, tolerability and anti-drug antibody formation were monitored. In February 2020, Catalyst Biosciences reported positive interim efficacy and safety data from its Phase 2b trial in an oral presentation at the 13th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD).

Dr. Blouse will present data from preclinical studies of Catalyst's hemophilia B gene therapy CB 2679d-GT, a novel chimeric AAV capsid expressing the Company's proprietary enhanced potency FIX variant that may reduce the vector dose required in gene therapy, while maintaining high FIX levels.

A copy of the presentation materials can be accessed on the <u>Events and Presentations</u> section of the Catalyst website once the presentations conclude.

About Catalyst Biosciences

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet needs in rare hematologic and systemic complement-mediated disorders. Our protease engineering platform includes development programs in hemophilia, a research program on subcutaneous (SQ) systemic complement inhibitors and a partnered preclinical development program with Biogen for dry age-related macular degeneration (AMD). One of our key competitive advantages is that the product candidates generated by our protease engineering platform have improved functionality and potency. These characteristics allow for improved dosing of our candidates including SQ systemic delivery of recombinant coagulation factors and complement inhibitors, low-dose high activity gene therapy constructs and less frequently dosed intravitreal therapeutics. Our most advanced asset, SQ MarzAA has successfully completed Phase 2 development in prophylaxis, significantly reducing the annualized bleed rate (ABR) in individuals with hemophilia A or B with inhibitors. Following regulatory guidance from the FDA and EMA, we recently announced the design of a Phase 3 registration study that is planned for late 2020. Subcutaneous dalcinonacog alfa (DalcA) is being developed for the treatment of hemophilia B and has demonstrated efficacy and safety in a Phase 2b clinical trial that has completed dosing and all participant activities. We have a discovery stage Factor IX gene therapy construct - CB 2679d-GT - for hemophilia B that has demonstrated superiority compared with the Padua variant in preclinical models. Finally, we have a global license and collaboration agreement with Biogen for the development and commercialization of anti-complement Factor 3 (C3) pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry AMD. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential uses and benefits of MarzAA and DalcA to address hemophilia indications and other rare bleeding disorders, including the potential benefits of SQ dosing, plans for the Phase 3 trial of MarzAA in late 2020, and about Catalyst's collaboration with Biogen. 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, including, but not limited to, the risk that trials and studies may be delayed as a result of the COVID-19 virus and other factors, that trials may not have satisfactory outcomes, that complete data from the Phase 2b trial of DalcA may not replicate previously reported partial results or that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of DalcA or MarzAA, including the generation of neutralizing antibodies, which has been observed in patients treated

with DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, including as a result of delays in development and manufacturing resulting from COVID-19 and other factors, the risk that Biogen will terminate Catalyst's agreement with them, competition and other risks described in the "Risk Factors" section of the Company's quarterly report filed with the Securities and Exchange Commission on May 11, 2020, and in 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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Source: Catalyst Biosciences, Inc.