Catalyst Biosciences Presents Positive Final Data from its Phase 2b Trial of Subcutaneous Dalcinonacog Alfa (DalcA) at the World Federation of Hemophilia Virtual Summit 2020

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SOUTH SAN FRANCISCO, Calif., June 15, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced final efficacy and safety data from its Phase 2b trial of DalcA, a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of Hemophilia B. The poster was presented at the World Foundation of Hemophilia Virtual Summit, taking place from June 14 -19, 2020.

The poster, entitled: “Phase 2b Trial to evaluate the safety and factor IX levels of a daily subcutaneous prophylaxis treatment regimen of dalcinonacog alfa in Hemophilia B” presented by Howard Levy, M.B.B.Ch., Ph.D., M.M.M., chief medical officer, Catalyst Biosciences highlights results from the study.

Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12% in all participants, with FIX levels of up to 27% and a half-life of 2.5 to 5.1 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. Injection volumes were less than 1 mL. One subject withdrew on day 7 after reporting injection site reactions (ISR) from the first 3 SQ doses. No neutralizing anti-drug antibodies were detected and no serious adverse events were reported. Some subjects reported mild ISR of pain and/or redness, primarily with the initial injections. No thrombotic events occurred and blood coagulation markers of d-dimer, prothrombin fragment 1+2, thrombin-antithrombin and fibrinogen did not show any prothrombotic signals.

“The trial data showed excellent efficacy and a clean safety profile, all subjects achieved steady state FIX activity levels exceeding the primary endpoint of 12%. A simple, small volume SQ therapy to provide protective, FIX levels is a potentially transformational improvement in the management of Hemophilia B,” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst.

The trial 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.

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

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 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 administration 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. 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 for SQ DalcA to transform treatment for patients with Hemophelia B, plans to enroll the begin the Phase 3 trial of MarzAA in late 2020, the potential uses and benefits of MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously, the superiority of CB 2679d-GT over other gene therapy candidates and the Company’s collaboration with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry age-related macular degeneration. 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 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, 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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