Catalyst Biosciences Completes Phase 2b Trial of Subcutaneous Factor IX Dalcinonacog Alfa (DalcA)

April 21, 2020

Final results to be presented during the second quarter

SOUTH SAN FRANCISCO, Calif., April 21, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), a biopharmaceutical company developing novel subcutaneous (SQ) therapies for hemophilia and other bleeding disorders, today announced completion of dosing and the 30-day follow-up period for its Phase 2b trial of SQ dalcinonacog alfa (DalcA).

“We are pleased to have successfully completed the DalcA Phase 2b trial during this challenging pandemic and remain on track to report final results later this quarter,” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. ”Interim trial data presented at European Association for Haemophilia and Allied Disorders (EAHAD) 2020 earlier this year clearly demonstrated the potential for DalcA to significantly change the treatment paradigm in hemophilia B; we look forward to continuing its development.”

The open-label Phase 2b study was designed to evaluate the ability of DalcA to maintain steady state protective 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. Data presented at the EAHAD Congress in February showed that daily SQ dosing of DalcA achieved effective prophylaxis with FIX activity levels ranging from 14-28% and zero bleeds. No neutralizing antibodies were detected and the treatment was well tolerated. The half-life of SQ DalcA ranged from 70-112 hours, suggesting the potential for lower or less frequent dosing.

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 and a research program on subcutaneous (SQ) systemic complement inhibitors. One of our key competitive advantages is that our product candidates made using our protease engineering platform have improved functionality and potency. These characteristics allow for SQ delivery, which is less invasive, faster to treat, and more convenient than intravenous (IV) drugs currently on the market. Our lead asset, MarzAA has completed Phase 2 development in prophylaxis and met its primary endpoint of significantly reducing the annualized bleed rate (ABR) in individuals with hemophilia A or B with inhibitors. Our second hemophilia asset, SQ 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 an early stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B that has demonstrated superiority compared with the Padua variant in preclinical models. We also have a global license and collaboration agreement with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry age-related macular degeneration. 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 plans to present final results from the Phase 2b clinical trial of DalcA later this quarter, the potential for positive results from the Phase 2b clinical trial of DalcA and for SQ DalcA to change the treatment paradigm for hemophilia B, 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 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 annual report filed with the Securities and Exchange Commission on February 20, 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.