# Catalyst Biosciences Completes MarzAA Pharmacokinetic & Pharmacodynamic Study

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**Results support subcutaneous dosing regimen of the Phase 3 Registrational trial**

SOUTH SAN FRANCISCO, Calif., June 10, 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 its Phase 1 MAA-102 study for Marzeptacog alfa (activated) (MarzAA). The results support the use of SQ MarzAA to treat episodic bleeding. The company is on track to enroll the first patient in its Phase 3 registration trial evaluating the efficacy of SQ MarzAA to treat bleeding events in individuals with hemophilia A or B with inhibitors in 2020.

"Successful completion of our Phase 1 study, in the midst of the global coronavirus pandemic, demonstrates the commitment of our team and is one more step towards enrolling the first patient in our pivotal Phase 3 trial for MarzAA later this year," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We believe MarzAA's rapid uptake and extended half-life with SQ administration has the potential to disrupt the multi-billion dollar hemophilia and bleeding disorders market by addressing clear unmet needs for treatment and prevention of bleeding."

The Phase 1 study was designed to evaluate the safety, pharmacokinetics and pharmacodynamics of single ascending dose levels of MarzAA and twice and thrice dosing of 60 µg/kg at 3-hourly intervals in individuals with Hemophilia A or B with or without inhibitors. Catalyst reported positive interim data at the 13th Annual Congress of the European Association of Haemophilia and Allied Disorders (EAHAD) on February 5, 2020 and final results will be presented at an upcoming scientific meeting.

**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 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 plans to enroll the first patient in the Phase 3 trial of MarzAA before year-end, plans to present final results from the Phase 1 trial of MarzAA at an upcoming scientific meeting, 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, 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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