Catalyst Biosciences Announces First Patient Dosed in Pivotal Phase 3 Registration Study of SQ MarzAA in Individuals with Hemophilia A or B with Inhibitors

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SOUTH SAN FRANCISCO, Calif., May 05, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the dosing of the first patient in the Crimson 1 Study, the Company's Phase 3 registration trial (MAA-304 - Crimson 1) of Marzeptacog alfa (activated) – or MarzAA, the Company's subcutaneously (SQ) administered next-generation engineered recombinant coagulation Factor VIIa (rFVIIa).

"Dosing the first patient in our pivotal Phase 3 study of MarzAA is an important milestone for Catalyst given the significant challenges encountered in conducting clinical trials during the ongoing global Covid-19 pandemic," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "MarzAA is the only SQ-delivered therapy in development for the episodic treatment of bleeding events and if successful, could fundamentally change patients' lives. We look forward to providing further updates on the MAA-304 study, the associated Phase 1/2 study (MAA-202) in other rare bleeding disorders, and in our growing complement pipeline later this year."

Crimson 1 is an open-label, global, multi-center, randomized, cross-over study, designed to evaluate the safety and efficacy of SQ MarzAA for episodic treatment of spontaneous or traumatic bleeding episodes, in adults and adolescents with congenital Hemophilia A or B with inhibitors, compared with standard of care. The study will assess the effectiveness of SQ MarzAA, using up to three doses to treat a bleeding episode, compared with IV FEIBA or up to three doses of IV rFVIIa. Catalyst anticipates the submission of its first report to the Data and Safety Monitoring Board (DSMB) in 2021.

About Catalyst Biosciences, the Protease Medicines company
Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare disorders of the complement and coagulation systems. Our protease engineering platform has generated two late-stage clinical programs, including MarzAA, an SQ administered next-generation engineered rFVIIa for the episodic treatment of bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration, an improved complement factor I protease for SQ replacement therapy in patients with CFI deficiency, and C4b-degraders designed to target disorders of the classical complement pathway, as well as other complement programs in discovery.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential benefits of products based on Catalyst's engineered protease platform, plans to enroll the Phase 3 open-label trial of MarzAA, and plans to submit the first report to the Data and Safety Monitoring Board (DSMB) in 2021. 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 the Phase 3 trial of MarzAA and other trials may be delayed or terminated as a result of COVID-19, competitive products and other factors, that Catalyst may not submit its first report to the DSMB as planned, 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 MarzAA, including the generation of neutralizing antibodies, 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 trial enrollment, development and manufacturing resulting from COVID-19 and other factors, competition and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2021, 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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