

Catalyst Biosciences Announces First Patient Dosed in Marzeptacog Alfa (Activated) Phase 1/2 Study in Factor VII Deficiency, Glanzmann Thrombasthenia and Hemophilia A treated with Hemlibra

May 18, 2021

SOUTH SAN FRANCISCO, Calif., May 18, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the initiation of dosing in the Company's Phase 1/2 study (MAA-202) of marzeptacog alfa (activated) – known as "MarzAA." MarzAA is a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa). MAA-202 is a Phase 1/2 open-label study designed to evaluate the pharmacokinetics (PK), pharmacodynamics (PD), safety and efficacy of SQ MarzAA for treatment of bleeding in FVII deficiency, Glanzmann Thrombasthenia, and Hemophilia A with inhibitor patients receiving Hemlibra[®] prophylaxis. This study, along with Catalyst's ongoing Phase 3 study MAA-304 evaluating MarzAA for the treatment of bleeding episodes in patients with Hemophilia A or B with inhibitors, is a key part of the Company's strategy to realize the full potential of MarzAA to improve the lives of patients with inherited bleeding disorders.

"MarzAA is the only bypassing agent under development for the episodic treatment of bleeding events that can be rapidly administered subcutaneously and, if successful, will address a significant unmet medical need," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We look forward to providing updates on the MarzAA clinical development program, including reporting interim data from MAA-202 later this year."

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, and plans to conduct the MAA-202 and MAA-304 clinical trials of MarzAA. 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 one or both of the clinical trials of MarzAA may be delayed or terminated as a result of COVID-19, competitive products 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 6, 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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Source: Catalyst Biosciences, Inc.