Catalyst Biosciences Presents Crimson 1 Phase 3 Study Design at the 62nd Annual American Society of Hematology Conference

December 7, 2020

SOUTH SAN FRANCISCO, Calif., Dec. 07, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) presented a poster today at the 62nd Annual American Society of Hematology (ASH) meeting, held virtually December 5-8, 2020, highlighting its Phase 3 Study, Crimson 1. The study will evaluate Marzeptacog alfa (activated) – or MarzAA, the Company's subcutaneously administered next-generation engineered coagulation Factor VIIa (FVIIa).

In the poster, entitled "*The Crimson 1 Study: A Phase 3 Study to Evaluate the Efficacy and Safety of Subcutaneous Marzeptacog Alfa (activated) for on-Demand Treatment and Control of Bleeding Episodes in Subjects with Hemophilia A or Hemophilia B, with Inhibitors*," Linda Neuman, MD, vice president of clinical development at Catalyst Biosciences, presented the rationale and design of the currently enrolling trial.

The Phase 3 study is an open-label, global, multi-center, randomized, cross-over study to evaluate the efficacy and safety of MarzAA for on-demand treatment of spontaneous or traumatic bleeding episodes, in adolescents and adults with congenital Hemophilia A or B with inhibitors, compared to Standard of Care. The study will enroll approximately 60 subjects to treat 244 eligible bleeding episodes with each treatment. The primary endpoint for the trial is the percentage of treated bleeds resulting in effective hemostasis at the 24-hour timepoint. The objective of the trial is to demonstrate non-inferiority of MarzAA compared to Standard of Care.

"MarzAA is the only SQ delivered therapy in development for on-demand treatment of bleeding events and could become an important addition to the treatment landscape for patients," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We're looking forward to announcing our continued progress."

About Catalyst Biosciences

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare hematologic and complement-mediated disorders. Our protease engineering platform generated two late-stage clinical programs in hemophilia; a research program on engineering of subcutaneous (SQ) complement inhibitors; a discovery stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B, and a partnered preclinical development program with Biogen for dry age-related macular degeneration (AMD). The product candidates generated by our protease engineering platform have improved functionality and potency that allow for: SQ administration of recombinant coagulation factors and complement inhibitors; low-dose, high activity gene therapy constructs; and less frequently dosed intravitreal therapeutics.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about Catalyst's plans for a Phase 3 study of MarzAA for on-demand treatment of spontaneous or traumatic bleeding episodes, the potential for MarzAA to effectively and therapeutically treat hemophilia subcutaneously, 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 COVID-19 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 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 November 5, 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.