Catalyst Biosciences Presents Pre-clinical SQ Treatment of Bleeds Data from its Marzeptacog alfa (activated) (MarzAA) Program at the 14th Annual EAHAD Congress

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SOUTH SAN FRANCISCO, Calif., Feb. 03, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today presented positive pre-clinical data from its Marzeptacog alfa (activated) – MarzAA, program, the Company's subcutaneously (SQ) administered next-generation engineered activated coagulation Factor VII (FVIIa) for the treatment of episodic bleeding that is entering a Phase 3 registration trial. The data were presented by Tom Knudsen, D.V.M., Ph.D., vice president of translational research and Howard Levy, M.B.B.Ch., Ph.D., M.M.M., chief medical officer in poster sessions at the virtual 14th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD).

The poster, "Subcutaneous Marzeptacog Alfa (Activated) is Effective for On-Demand Treatment of Spontaneous Bleeding in Hemophilia A (HA) Rats," showed that SQ MarzAA was superior to vehicle (p=0.007) and effective for the management of spontaneous mild, moderate, and severe bleeding in HA rats. Notably, the rats have a human-like bleeding phenotype and most rats needed only a single SQ dose of MarzAA to achieve efficacious bleeding control.

The poster, "Subcutaneous Marzeptacog Alfa (Activated) is Effective for On-Demand Treatment in Dogs with Hemophilia A," demonstrated that SQ MarzAA appeared to be consistently effective as an on-demand treatment of spontaneous bleeding in dogs with Hemophilia A. SQ MarzAA treatment rapidly improved all parameters of the thromboelastography (TEG), controlled bleeding, and improved the general condition of the dogs. TEG normalized in 3 of 5 dogs, was confounded by canine FVIII administration in one dog, and did not respond in another dog despite rapid cessation of bleeding. TEG R-time shortened to the same or shorter time than high dose (270 g/kg) intravenous NovoSeven.

"In hemophilia, spontaneous bleeding can occur even on prophylaxis, and there is a need for a safe and effective treatment that can be easily administered subcutaneously to manage breakthrough bleeding. The pre-clinical data we presented at EAHAD showed efficacy in controlling spontaneous bleeding," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We are dedicated to developing meaningful SQ therapy options for individuals living with hemophilia and other rare bleeding disorders."

MarzAA is entering a registrational Phase 3 trial (MAA-304) to treat spontaneous bleeds in patients with Hemophilia A or B with inhibitors (Crimson 1). Catalyst also plans to initiate a Phase 1/2 trial of MarzAA in Factor VII Deficiency, Glanzmann Thrombasthenia, and Hemophilia A with inhibitor patients on Hemlibra prophylaxis for treatment of episodic bleeding (MAA-202).

A copy of the presentation materials can be accessed on the Events and Presentations section of the Catalyst website.

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, a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a pre-clinical C3-degrader program partnered with 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 development.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about Catalyst's product candidates, including effects of SQ dosing, clinical trial plans for MarzAA, and the other benefits of its protease engineering platform. 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, 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, 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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