FDA Grants Catalyst Biosciences Orphan Drug Designation for MarzAA for the Treatment of Factor VII Deficiency

September 28, 2021

SOUTH SAN FRANCISCO, Calif., Sept. 28, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Disease Designation (ODD) for its lead product candidate, subcutaneous Marzeptacog alfa (activated), or MarzAA, for the treatment of Factor VII Deficiency (FVIID). MarzAA was previously granted ODD and Fast Track Designation (FTD) for treatment of Hemophilia A/B with inhibitors and FTD for the treatment of FVIID.

"Receiving a second orphan drug designation in addition to two FTDs for MarzAA demonstrates its potential in treating multiple rare bleeding disorders" said Nassim Usman, Ph.D., president and chief executive officer of Catalyst.

The FDA grants Orphan Drug Designation to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides benefits to drug developers designed to support the developments of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

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 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 proteases from our ProTUNE™ C3b-C4b degrader and ImmunoTUNE™ C3a-C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways 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, without limitation, statements about the product candidates of Catalyst and the benefits of its protease engineering platform; potential benefits of MarzAA and plans to commercialize 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 trials and studies may be delayed as a result of COVID-19, competitive products and other factors, that trials may not have satisfactory outcomes, the significance of the second orphan drug designation for MarzAA, the risk Catalyst may elect to terminate or postpone ongoing development programs, including development of MarzAA, the risk that Catalyst will need to raise additional capital, which may not be available on favorable terms if at all; the risk that costs required to develop or manufacture Catalyst'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 may terminate the agreement with Catalyst, and other risks described in the "Risk Factors" section of Catalyst's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 4, 2021, the Quarterly Report on Form 10-Q filed with the SEC on August 5, 2021 and in other filings filed from time to time with the SEC. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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