Catalyst Biosciences Receives Rare Pediatric Disease Designation for CB 4332 for the Treatment of CFI Deficiency

January 25, 2022

SOUTH SAN FRANCISCO, Calif., Jan. 25, 2022 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation (RPDD) for CB 4332 for the treatment of Complement Factor I (CFI) deficiency (CFID).

“The granting of the Rare Pediatric Disease Designation for CB 4332 underscores the significant unmet medical need in pediatric patients with CFID. We are focused on efficiently advancing the development of CB 4332 and our complement medicines portfolio in a number of complement-driven diseases in hematology, nephrology and ophthalmology. We are pleased with the FDA's assessment of CB 4332 as a potential therapy for underserved pediatric patients with CFID and the granting of the RPDD,” said Nassim Usman, Ph.D., chief executive officer of Catalyst Biosciences.

Under the FDA's rare pediatric disease designation program, the FDA may grant a priority review voucher to a sponsor who receives a product approval for a rare pediatric disease. A rare pediatric disease is defined as a serious or life-threatening condition that affects less than 200,000 individuals in the U.S. per year and who are primarily less than 18 years of age.

About Catalyst Biosciences, the Protease Medicines company
Catalyst is a research and clinical development biopharmaceutical company focused on developing protease therapeutics to address unmet medical needs in disorders of the complement system. Proteases are natural regulators of this biological system. We engineer proteases to create improved or novel molecules to treat diseases that result from dysregulation of the complement cascade. Our complement pipeline consists of several proteases that regulate the complement cascade including our improved Complement Factor I protease CB 4332 for patients with deficiencies in CFI, a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration (dAMD), and proteases from our ProTUNE™ C3b/C4b degrader and ImmunoTUNE™ C3a/C5a degrader platforms designed to target other disorders of the complement or inflammatory pathways.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include, without limitation, those regarding plans for clinical development of CB 4332, the potential to receive a priority review voucher, and the continued generation of candidates to treat diseases that result from dysregulation of the complement cascade, as well as statements about the benefits of our 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 clinical trials and preclinical studies may be delayed as a result of COVID-19, competitive products, and other factors, that Biogen could terminate our agreement for the development of CB 2782-PEG, that the Company's complement degraders are not yet in human clinical trials and will require additional manufacturing validation and preclinical testing before entering human clinical trials and multiple clinical trials before being approved, that the Company may need to raise additional capital, 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 (the "SEC") on March 4, 2021, the Quarterly Report on Form 10-Q filed with the SEC on November 12, 2021, and in other filings filed from time to time with the SEC. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

Contact:

Ana Kapor
Catalyst Biosciences, Inc.
investors@catbio.com