



Catalyst Biosciences Receives Patent in the European Union for Its Factor IX Portfolio

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FIX patent including DalcA and CB 2679d-GT, now issued in all major markets

SOUTH SAN FRANCISCO, Calif., April 28, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: C BIO), a biopharmaceutical company developing novel subcutaneous (SQ) therapies for hemophilia and other bleeding disorders, today announced the European Patent Office has issued the Company a FIX portfolio patent covering the lead clinical candidate, dalcinonacog alfa (DalcA) for Factor IX (FIX) replacement therapy, and the Company's FIX preclinical gene therapy candidate, CB 2679d-GT.

"This newly issued EU patent expands the breadth of our Factor IX intellectual property portfolio. We now have broad patent coverage in all major markets including the United States, the European Union, Japan and China," said Nassim Usman, Ph.D., Catalyst's president and chief executive officer. "DalcA has successfully completed a Phase 2b clinical trial and CB 2679d-GT is progressing into non-human primate studies. We believe that having both a potent recombinant SQ FIX and a best in class FIX gene therapy is the right strategy to build a hemophilia B portfolio."

Catalyst is developing DalcA, a next-generation SQ FIX therapy for the treatment of hemophilia B. The Company has successfully completed a Phase 2b trial. Interim clinical data was presented at the European Association for Haemophilia Allied Disorders (EAHAD) in February 2020, and final results will be reported this quarter.

The Company's proprietary FIX gene therapy construct CB 2679d-GT is being developed for the treatment of hemophilia B and has demonstrated superiority compared with the Padua variant in preclinical models. The Company recently presented preclinical data at EAHAD in February 2020 demonstrating that a proprietary chimeric AAV capsid licensed from Stanford University expressing the CB 2679d-GT FIX variant may significantly reduce the vector dose required of a gene therapy treatment, while maintaining high factor activity levels.

About Catalyst Biosciences

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet needs in rare hematologic and systemic complement-mediated disorders. Our protease engineering platform includes development programs in hemophilia and a research program on subcutaneous (SQ) systemic complement inhibitors. One of our key competitive advantages is that our product candidates made using our protease engineering platform have improved functionality and potency. These characteristics allow for SQ delivery, which is less invasive, faster to treat, and more convenient than intravenous (IV) drugs currently on the market. Our most advanced asset, MarzAA has successfully completed Phase 2 development in prophylaxis, significantly reducing the annualized bleed rate (ABR) in individuals with hemophilia A or B with inhibitors. Following regulatory guidance from the FDA and EMA, the company recently announced the design of a Phase 3 registration study that is planned for late 2020. SQ dalcinonacog alfa (DalcA) is being developed for the treatment of hemophilia B and has demonstrated efficacy and safety in a Phase 2b clinical trial that has completed dosing and all participant activities. We have an early stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B that has demonstrated superiority compared with the Padua variant in preclinical models. We also have a global license and collaboration agreement with Biogen for the development and commercialization of anti-complement Factor 3 (C3) pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry age-related macular degeneration. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about patent coverage for DalcA and CB 2679d-GT, plans to present final results from the Phase 2b clinical trial of DalcA later this quarter, the potential for positive results from the Phase 2b clinical trial of DalcA and for SQ DalcA to change the treatment paradigm for hemophilia B, the potential uses and benefits of MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously, the potential use of CB 2679d-GT to treat hemophilia B and its superiority over other gene therapy candidates, 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 the COVID-19 virus and other factors, that trials may not have satisfactory outcomes, that complete data from the Phase 2b trial of DalcA may not replicate previously reported partial results or that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of DalcA or MarzAA, including the generation of neutralizing antibodies, which has been observed in patients treated with DalcA, 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 patents may be invalidated or found unenforceable after they are granted, the risk that Biogen will terminate Catalyst's agreement with them, competition and other risks described in the "Risk Factors" section of the Company's annual report filed with the Securities and Exchange Commission on February 20, 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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