Catalyst Biosciences Appoints Charles Democko, Senior Vice President, Regulatory Affairs

June 22, 2020

SOUTH SAN FRANCISCO, Calif., June 22, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced the appointment of Mr. Charles Democko as Senior Vice President, Regulatory Affairs.

Mr. Democko brings over 20 years of regulatory affairs experience in the development of both biologics and small molecules ranging from pre-IND through commercial stage companies across several therapeutic areas. Mr. Democko will lead the regulatory efforts for the Company's rare hematologic and systemic complement-mediated disorders portfolio.

"As we plan for several important milestones in our next phase of growth, Charles' background and track record of successful marketing applications across many different therapeutic indications will be very valuable to Catalyst."

Mr. Democko commented, "Catalyst has an expansive pipeline of differentiated product candidates. I am looking forward to leading the Company's regulatory affairs efforts, which are growing and expanding in the organization."

Mr. Democko joins Catalyst from CytomX, where he led the Company's regulatory affairs and quality. Prior to CytomX, Mr. Democko was a Vice President of Regulatory Affairs at Ascendis, KaloBios, Novacea, PharmacoFore, and Connetics. Earlier in his career, Mr. Democko held regulatory affairs positions at Theravance, Elan and Genentech. Mr. Democko oversaw successful marketing applications for Activase (ischemic stroke), Myobloc (cervical dystonia), Olux (whole-body psoriasis) and Evoclin (acne), conduct of over 30 high-level meetings with FDA, EMA, and EU competent authorities, and the corporate presentation at the Activase ischemic stroke FDA advisory committee meeting, which resulted in a unanimous recommendation for approval. Mr. Democko holds a B.S. from Ohio State University.

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, a research program on subcutaneous (SQ) systemic complement inhibitors and a partnered preclinical development program with Biogen for dry age-related macular degeneration (AMD). One of our key competitive advantages is that the product candidates generated by our protease engineering platform have improved functionality and potency. These characteristics allow for improved dosing of our candidates including SQ systemic administration of recombinant coagulation factors and complement inhibitors, low-dose, high activity gene therapy constructs, and less frequently dosed intravitreal therapeutics. Our most advanced asset, SQ 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 U.S. Food and Drug Administration and European Medicines Agency, we recently announced the design of a Phase 3 registration study that is planned for late 2020. Subcutaneous dalcinonacog alfa (DalcA) is being developed for the treatment of Hemophilia B and has demonstrated efficacy and safety in a Phase 2b clinical trial. We have a discovery stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B, that has demonstrated superiority compared with the Padua variant in preclinical models. Finally, we 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 AMD.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential for SQ DalcA to transform treatment for patients with Hemophilia B, plans to enroll the begin the Phase 3 trial of MarzAA in late 2020, the potential uses and benefits of MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously, the superiority of CB 2679d-GT 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 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 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 May 11, 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.