Catalyst Biosciences Presents Data at the International Society for Thrombosis and Haemostasis (ISTH) Virtual Congress

July 13, 2020

Subcutaneous marzeptacog alfa (activated) (MarzAA) rapidly achieves and maintains therapeutic levels

Data confirm Phase 3 study design to treat acute bleeding events in hemophilia

SOUTH SAN FRANCISCO, Calif., July 13, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), today presented two posters at the International Society for Thrombosis and Haemostasis (ISTH) Virtual Congress being held July 12-14, 2020.

The first poster entitled: "*Phase 1 study to evaluate the pharmacokinetics, pharmacodynamics, and safety of ascending doses of subcutaneous marzeptacog alfa (activated) in adult subjects with hemophilia*" (PB0941), included the final data from MAA-102 and was presented by Linda Neuman, M.D., M.B.A., vice president, clinical development, Catalyst Biosciences. This study was conducted in adult subjects with Hemophilia A or B, with or without inhibitors to evaluate the pharmacokinetics, pharmacodynamics, and safety of a single IV dose and ascending SQ (single and multiple) doses of MarzAA. The final data demonstrated the potential of subcutaneous marzeptacog alfa (activated) (MarzAA) to rapidly achieve and maintain therapeutic levels to treat acute bleeding events in hemophilia and confirms the dosing regimen chosen for the upcoming Phase 3 trial, Crimson 1.

The second poster, entitled: "*Marzeptacog alfa (activated) population pharmacokinetics (PK): Simulations for dose selection in Phase 3 trials*," was presented by Tom Knudsen, DVM, Ph.D., vice president of translational research, Catalyst Biosciences. A population PK model was developed and used for clinical trial simulations. Based on simulating PK for SQ MarzAA in 1000 subjects, the model confirmed that target levels for hemostasis may be rapidly achieved and sustained for over 24 hours in the upcoming Phase 3 Crimson 1 trial using 60 µg/kg dosed SQ once, twice or three times at 3-hour intervals.

"The MAA-102 PK results and population PK simulations confirm that we have optimized dosing for our Phase 3 MarzAA trial, where we expect to treat the first patient in late 2020," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "MarzAA addresses an important unmet need of treating bleeding events subcutaneously and represents a significant market opportunity in several bleeding disorders."

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

About Catalyst Biosciences
Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet needs in rare hematologic and complement-mediated disorders. Our protease engineering platform includes two late-stage clinical programs in hemophilia; a research program on engineering of subcutaneous (SQ) complement inhibitors; and a partnered preclinical development program with Biogen for dry age-related macular degeneration (AMD). The product candidates generated by our protease engineering platform have improved functionality and potency that allow for: SQ administration of recombinant coagulation factors and complement inhibitors; low-dose, high activity gene therapy constructs; and less frequently dosed intravitreal therapeutics. Our most advanced product candidate is marzeptacog alfa (activated) (MarzAA), a next-generation SQ FVIIa entering a Phase 3 registration study in late 2020. Our next late-stage product candidate is dalcinonacog alfa (DalcA), a next-generation SQ FIX, which has demonstrated efficacy and safety in a Phase 2b clinical trial in individuals with Hemophilia B. 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.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential benefits of products based on Catalyst's engineered protease platform, plans to enroll the first patient into a Phase 3 registration study of MarzAA in late 2020, the potential for MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously, the potential of subcutaneous marzeptacog alfa (activated) (MarzAA) to rapidly achieve and maintain therapeutic levels to treat acute bleeding events in hemophilia, 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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