Catalyst Biosciences Hosts Research & Development Day Focused on Factor VIIa and Factor IX Hemophilia Programs

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SOUTH SAN FRANCISCO, Calif., Dec. 18, 2018 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, is hosting a Research & Development (R&D) Day today in New York to provide updates on its Factor IX (FIX) dalcinonacog alfa (DalcA) and Factor VIIa (FVIIa) marzeptacog alfa (activated) (MarzAA) hemophilia programs.

Members of the Catalyst management team, including, Nassim Usman, Ph.D., chief executive officer; Howard Levy, M.B.B.Ch., Ph.D., M.M.M., chief medical officer; Fletcher Payne, chief financial officer; and Grant Blouse, Ph.D., vice president of translational research, will be presenting beginning at 12:00 p.m. EST. A live and archived webcast of the event may be accessed here and on the Events and Presentations section of the Catalyst website.

“The results of our extensive DalcA immunogenicity risk assessment revealed a similar low immunogenicity potential compared with BeneFIX and other commercial wildtype FIXs; therefore, we will be moving forward with the clinical development of DalcA,” said Dr. Usman. “We plan to initiate a Phase 2b trial that will include 28 days of daily subcutaneous dosing in the first quarter of 2019. Based on the efficacy data that we have previously shown in which subjects achieved high mild hemophilia FIX activity, we believe that DalcA has the potential to provide a conveniently-dosed subcutaneous prophylactic treatment option for those suffering from hemophilia B.”

Dr. Usman continued, “Given the promising interim results from our Phase 2/3 study of MarzAA, in which all five subjects that have completed dosing experienced clinically significant reductions in their annualized bleed rates, and the results of our commercial assessment, showing a several hundred million dollar revenue forecast globally, we believe that MarzAA has significant clinical and commercial potential.”

Select R&D Day Highlights

DalcA

• A comprehensive immunogenicity risk assessment to investigate the development of neutralizing antidrug antibodies in Cohort 6 of the Phase 1/2 program concluded:

- The DalcA drug product does not appear to be inherently immunogenic.
- *In silico, in vitro* and *ex vivo* analyses indicate that the immunogenicity risk for DalcA is similar to commercial wildtype recombinant FIX products.
- The DalcA drug product quality is similar to marketed FIX products.
- 7-day subcutaneous non-human primate toxicology studies showed that DalcA subcutaneous injections were well tolerated.

• Catalyst plans to move forward with clinical development of DalcA to further evaluate the safety and efficacy of the product in a Phase 2b study that is expected to begin in Q1 2019.

MarzAA

• In the Phase 2 portion of the Phase 2/3 trial of MarzAA for the treatment of hemophilia A or B with inhibitors:

- Nine subjects have been enrolled to date (median annualized bleed rate of 16.25; range of 12.2-27.7).
- Of the five subjects that have completed dosing, all had clinically significant reductions in annualized bleed rate (ABR).
- Two subjects are currently dosing and others are undergoing screening.
- After more than 325 subcutaneous injections, no antidrug antibodies have been detected, and only one injection site reaction of swelling that resolved without sequelae has occurred.

• Catalyst plans to conduct a global Phase 3 clinical study assessing reductions in ABR in 20-40 patients with hemophilia with six months of daily subcutaneous dosing of MarzAA.

About Catalyst Biosciences
Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. 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 the relative safety of DalcA compared with BeneFIX and other recombinant Factor IX products, Catalyst’s plans to commence a Phase 2b clinical trial of DalcA in the first quarter of 2019, the potential for DalcA to provide a conveniently-dosed subcutaneous prophylactic treatment option for patients suffering from hemophilia B, the potential for MarzAA to provide prophylaxis therapy in patients with hemophilia A or B with inhibitors, the potential commercial market for MarzAA, and plans to continue the ongoing Phase 2/3 clinical trial of MarzAA and for a Phase 3 clinical

study of 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 from the forward-looking statements that the Company makes, including, but not limited to, the risk that trials and studies may be delayed and 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 MarzAA or DalcA, including the generation of 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, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 filed with the Securities and Exchange Commission on November 1, 2018, and with 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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