Catalyst Biosciences Presents Positive Data from its Phase 2b Trial of Subcutaneous Dalcinonacog Alfa (DalcA) and Marzeptacog alfa (activated) (MarzAA) Programs at the 13th Annual EAHAD Congress

February 7, 2020

Enrollment in the DalcA trial is complete; results demonstrate DalcA provides Factor IX (FIX) activity exceeding the efficacy endpoint with no anti-drug antibodies

Company to host investor call and webcast on Friday, February 7 at 8:30 a.m. ET

SOUTH SAN FRANCISCO, Calif., Feb. 07, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced positive efficacy and safety data from its Phase 2b trial of DalcA, a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of hemophilia B. The data were presented by Johnny Mahlangu, M.B.B.Ch., M.Med, F.C.Path, professor of haematology, faculty of health sciences, head of the School of Pathology at the University of Witwatersrand in Johannesburg, South Africa, and principal investigator in the clinical trial in an oral presentation at the 13th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) in The Hague, Netherlands.

Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12%, with steady state FIX levels of up to 27% after 14 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. One subject withdrew on day 7. No anti-drug antibodies were detected and no serious adverse events were reported. Three subjects reported injection site reactions (ISRs), the majority of which were mild in severity and resolved without sequelae.

The open-label Phase 2b study was designed to evaluate the ability of DalcA to maintain steady state protective FIX levels above 12% in six individuals with severe hemophilia B. Each subject received a single intravenous dose, followed by daily SQ doses of DalcA for 28 days. Pharmacokinetics, pharmacodynamics, safety and tolerability of daily SQ dosing and anti-drug antibody formation are being monitored.

“The DalcA Phase 2b trial data presented today at EAHAD clearly demonstrate the potential for DalcA to significantly change the treatment paradigm for those suffering from hemophilia B,” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. “With the trial now fully enrolled and one final subject completing dosing, we will announce final data in the second quarter of this year.”

Dr. Usman continued, “We are very encouraged by the data presented at EAHAD from three of our programs and see 2020 as a pivotal year for our entire hemophilia franchise. In addition to the Phase 2b DalcA data, our SQ FVIIa marzeptacog alfa (activated) MarzAA candidate has demonstrated efficacy and safety in individuals with hemophilia A or B with inhibitors in a Phase 2 prophylaxis study, and this week we presented pharmacokinetic and pharmacodynamic data that support SQ MarzAA use in acute or on-demand settings. Our high-potency FIX gene therapy candidate, CB 2679d-GT is developing into a promising asset with encouraging pre-clinical data using a proprietary next-generation AAV capsid. Our entire team is committed to developing novel treatments in multiple rare bleeding disorders.”

In addition to the oral presentation on the Phase 2b DalcA data, Catalyst presented three posters at the EAHAD congress. Dr. Linda Neuman, vice president, clinical development, presented data from a Phase 1 study to evaluate the pharmacokinetics, pharmacodynamics, and safety of ascending doses of SQ MarzAA in adult subjects with hemophilia, which showed that SQ dosing reaches target levels to treat ongoing bleeding. Dr. Grant Blouse, vice president, translational research, presented data on SQ MarzAA demonstrating that on-demand treatment in Hemophilia A mice treated after a tail clip injury was as efficient as intravenous NovoSeven at reducing bleeding. Dr. Blouse also presented a poster on Hemophilia B gene therapy in mice demonstrating that a novel chimeric AAV capsid combined with the Company’s proprietary potency enhanced CB 2679d-GT FIX variant may reduce the vector dose required in gene therapy while maintaining high FIX levels.

A copy of the presentation materials can be accessed on the Events and Presentations section of the Catalyst website. Catalyst will host an investor call on Friday, February 7, at 8:30 a.m. ET.

Conference Call Details
The management team will host a conference call for investors on Friday, February 7 at 8:30 a.m. ET to discuss the DalcA and MarzAA data presented at EAHAD. Conference call, webcast and post-conference call replay details are as follows:

Domestic:	+1.877.425.9470
International:	+1.201.389.0878
Conference ID:	13698597
Webcast link:	http://public.viavid.com/index.php?id=137884

A webcast replay will be available for 30 days following the live event.

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 clinical-stage biopharmaceutical company focused on addressing unmet needs in rare diseases and systemic complement mediated disorders. Our protease engineering platform includes development programs in hemophilia and a research program on subcutaneous (SQ) systemic complement inhibitors. Our engineered coagulation factors are designed to overcome the significant limitations of current IV treatment options, facilitate prophylaxis, and ultimately deliver substantially better outcomes for patients using SQ dosing. Our lead asset, MarzAA has completed Phase 2 development having met its primary endpoint of significantly reducing the annualized bleed rate (ABR) in individuals with hemophilia A or B with inhibitors. Our second hemophilia asset, DalcA is in a Phase 2b clinical trial and is being developed for the treatment of hemophilia B. We also have a global license and collaboration agreement with Biogen for the development and commercialization of 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 the potential uses and benefits of DalcA to provide benefits and change the treatment paradigm for patients with hemophilia B and for MarzAA to treat patients with hemophilia A or B with inhibitors, the potential benefits of SQ dosing, statements about Catalyst's clinical trial status for DalcA, the potential for CB 2679d-GT to be a promising asset and the potential use of MarzAA as an on-demand therapy. 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 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 DalcA, or MarzAA, including the generation of antibodies, which has been observed in patients previously treated with DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other risks described in the "Risk Factors" section of the Company's quarterly report filed with the Securities and Exchange Commission on November 7, 2019, 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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