



## **Catalyst Biosciences and CMC Biologics Announce Manufacturing Agreement for Catalyst's Next-Generation Factor VIIa Product CB 813d**

May 24, 2016

*- Companies Committed to Establishing Manufacturing Capabilities for Next-Generation Factor VIIa CB 813d -*

*- Catalyst Plans to Initiate Clinical Pivotal Trial in Hemophilia A and B "Inhibitor" Patients in 2017 -*

SOUTH SAN FRANCISCO, Calif. and BOTHELL, Wash. and COPENHAGEN, Denmark, May 24, 2016 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a leading biotechnology company focused on discovering and developing novel protease therapeutics for treatments of serious medical conditions in the fields of hemostasis and anti-complement, and CMC ICOS Biologics, Inc. ("CMC Biologics"), a global leader in clinical and commercial manufacturing of therapeutic proteins, today announced that they have entered into a manufacturing agreement for the process transfer and cGMP manufacturing of CB 813d, Catalyst's next-generation long-acting Factor VIIa product. Catalyst is developing CB 813d for the treatment of hemophilia A and B inhibitor patients.

"We selected CMC Biologics as our manufacturing partner for CB 813d because of their demonstrated technical expertise in producing commercial coagulation factor proteins and the quality of their cGMP operations," said Andrew Hetherington, Catalyst's Vice President of Manufacturing Operations. "The successful transfer and manufacture of CB 813d is critical to meeting our clinical timelines as we advance our lead candidate towards a pivotal study."

"We are developing CB 813d to potentially treat both acute bleeding episodes and allow for prophylactic treatment compared to existing products and other therapies in development," said Nassim Usman, Ph.D., President & Chief Executive Officer of Catalyst. "We remain on track to initiate a Phase 2/3 clinical pivotal trial of CB 813d, our most advanced hemophilia product candidate, in 2017."

"We are delighted that Catalyst has selected CMC Biologics as their contract manufacturing organization for CB 813d as they prepare for a key clinical efficacy trial," said Gustavo Mahler, Ph.D., President & Chief Executive Officer of CMC Biologics. "CMC has a great deal of experience manufacturing similar blood coagulation factor products and we look forward to manufacturing Catalyst's next-generation Factor VIIa."

### **About CB 813d**

CB 813d, Catalyst's most advanced product candidate, is a next-generation Factor VIIa that successfully completed a Phase 1 clinical trial in 2015 in severe hemophilia A and B with and without inhibitors. CB 813d is initially being developed for the on-demand and prophylactic treatment of severe hemophilia A and B patients with inhibitors. CB 813d was designed to combine higher clot-generating activity at the site of bleeding and improved duration of action.

### **About Hemophilia and Factor Replacement Therapy**

Hemophilia, for which there is no cure, is a rare but serious bleeding disorder that results from a genetic or an acquired deficiency of a protein required for normal blood coagulation. There are two major types of hemophilia, A and B, that are caused by alterations in Factor VIII or Factor IX genes, respectively, with a corresponding deficiency in the affected proteins. The prevalence of hemophilia A and B in the United States is estimated to be around 20,000 people, with more than 400,000 cases worldwide. Hemophilia patients suffer from spontaneous bleeding episodes as well as substantially prolonged bleeding times upon injury. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in permanent, disabling joint damage and can become life threatening. Treatment usually involves management of acute bleeding episodes or prophylactic treatment through factor replacement therapy by infusion of patients' missing Factor VIII or IX. With the frequent infusion schedule of current therapies, adherence is difficult. In addition, convenient access to peripheral veins is often a problem, and many children require use of central venous access devices, with the concomitant risks of infection and thrombosis.

### **About Catalyst Biosciences**

Catalyst is a clinical-stage biopharmaceutical company focused on creating and developing novel medicines to address serious medical conditions. To date, Catalyst has focused its product development efforts in the fields of hemostasis, including the treatment of hemophilia and surgical bleeding, and inflammation, including prevention of delayed graft function in renal transplants and the treatment of dry age-related macular degeneration, a condition that can cause visual impairment or blindness. Catalyst's most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, which has successfully completed a Phase 1 clinical trial in severe hemophilia A and B patients. In addition to Catalyst's lead Factor VIIa program, Catalyst has two other next-generation coagulation factors, a Factor IX variant, CB 2679d/ISU 304, that is in advanced preclinical development, and a Factor Xa variant, that is in the advanced lead stage of development. For more information, please visit [www.catalystbiosciences.com](http://www.catalystbiosciences.com).

### **About CMC Biologics**

CMC Biologics is leading the industry among CMOs in reliability, technical excellence, and quality—Right and On Time. With facilities in the USA and Europe, the Company is a global CMO that provides fully integrated biopharmaceutical development and manufacturing solutions to clients around the world. The Company has proven expertise in delivering custom solutions for the scale-up and cGMP manufacture of protein-based therapeutics for pre-clinical, clinical trials and commercial production. The Company's wide range of integrated services includes cell line development, bioprocess development, formulation and comprehensive analytical testing. Clients can also benefit from CMC Biologics' proprietary CHEF1<sup>®</sup> expression system for mammalian production. CMC Biologics has fully segregated microbial fermentation and mammalian cell culture suites and offers both fed-batch and perfusion production processes. More detailed information can be found at [www.cmcbiologics.com](http://www.cmcbiologics.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statement of

historical facts, included in this press release regarding our strategy, future operations, and plans are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the ability of CMC to manufacture CB 813d, the potential success of manufacturing technology transfer to CMC, Catalyst's clinical trial timelines, and the potential uses and benefits of CB 813d and Catalyst's other products in development. 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 Catalyst makes, including, but not limited to, the risk that the technology transfer for manufacturing CB813d may not be successful, that trials and studies may be delayed and may not have satisfactory outcomes, that potential adverse effects may arise from the testing or use of Catalyst's products, the risk that costs required to develop or manufacture Catalyst's products will be higher than anticipated, competition and other factors that affect our ability to successfully develop and commercialize our product candidates described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the SEC on March 9, 2016. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

Catalyst Contacts:

Investors:

Fletcher Payne, CFO  
Catalyst Biosciences, Inc.  
650.871.0761  
[investors@catbio.com](mailto:investors@catbio.com)

Media:

Denise Powell  
Red House Consulting, LLC  
510.703.9491  
[denise@redhousecomms.com](mailto:denise@redhousecomms.com)

CMC Biologics Contact:

Robert Broeze, Ph.D.  
Senior Vice President, Global Business Development  
609.273.3414  
[bbroeze@cmcbio.com](mailto:bbroeze@cmcbio.com)



Catalyst Biosciences, Inc.