CMC Biologics Cleared for Commercial Manufacture of CSL Behring's FDA-Approved AFSTYLA®

- Bulk Drug Intermediate Produced in CMC Biologics' Copenhagen, Denmark Facility

COPENHAGEN, Denmark and BOTHELL, Wash. – June 15, 2016 – CMC Biologics, a global leader in clinical and commercial manufacturing of monoclonal antibodies, coagulation factors and other therapeutic proteins, today announced that it will supply bulk drug intermediate for CSL Behring's recently FDA-approved product, AFSTYLA® [Antihemophilic Factor (Recombinant), Single Chain], its novel long-lasting recombinant factor VIII single-chain therapy for adults and children with hemophilia A, to reduce the frequency of bleeding episodes; on-demand treatment and control of bleeding episodes; and the perioperative management of bleeding.

"Working together with CSL Behring to achieve this important commercial milestone has been a major focus for our entire team in Copenhagen," said Patricio Massera, PhD, Site Head & General Manager of CMC Biologics' Copenhagen facility. "We are proud to have played an important role on the clinical development and manufacturing of the recombinant factor VIII single-chain of AFSTYLA®."

CMC Biologics has an agreement with CSL Behring for the manufacture of the first intermediate of recombinant factor VIII single-chain drug substance. CMC Biologics' facility in Copenhagen, Denmark was inspected by the FDA as part of the approval for the commercial manufacture of AFSTYLA®.

"We are extremely pleased to help CSL Behring provide this critical treatment option to patients for management of hemophilia A," said Gustavo Mahler, PhD, President & Chief Executive Officer of CMC Biologics. "With marketed products manufactured in both our Seattle and Copenhagen facilities, we provide robust commercial solutions and experience for our clients on both continents. Our commitment to deliver on our client's products is prioritized across the entire organization."

About CMC Biologics

CMC Biologics is leading the industry among CDMOs in reliability, technical excellence, and quality — Right and On Time. With three facilities in the USA and Europe, the Company provides fully integrated biopharmaceutical development and manufacturing solutions to clients globally. The Company has proven expertise in delivering custom solutions for the scale-up and cGMP manufacture of protein-based therapeutics for pre-clinical, clinical, and commercial production. The Company's wide range of integrated services includes cell line development, bioprocess development, formulation development, and comprehensive analytical testing. Clients can also benefit from CMC Biologics' proprietary CHEF1® 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.

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