CMC Biologics Achieves Authorization for cGMP Commercial Manufacturing by the Danish Medicines Agency

Copenhagen biopharmaceutical manufacturing facility expanded to support growing customer demand for clinical and commercial production

Copenhagen, Denmark / Seattle, Washington USA – October 15, 2013 – CMC Biologics has received renewal of its manufacturing and importation authorization (MIA) for Good Manufacturing Practice (cGMP) production of clinical and commercial manufacturing from the Danish Medicines Agency (DKMA), a division of the Danish Health and Medicines Authority. The DKMA inspected CMC Biologics' optimized manufacturing and testing facilities in Copenhagen, Denmark in late May, and issued the certificate based on the positive outcome of the inspection.

"This important regulatory milestone helps drives our strategy to satisfy our customers' growing clinical and commercial cGMP manufacturing requirements, and takes this site to the next level as a global leader in commercial production of protein therapeutics," said Patricio Massera, General Manager of CMC Biologics Copenhagen. "We are committed to the highest quality standards and extremely pleased with the results of the agency's inspection."

CMC Biologics made an important capital investment in its biopharmaceutical manufacturing facility which optimizes segregation of unit operations and improves flow of materials and personnel. The enhanced layout now maintains a fully unidirectional return corridor and exit airlocks to achieve exceptional manufacturing quality standards. The updated MIA is available on the EudraGMP database at http://eudragmp.ema.europa.eu; authorization number 26415.

Massera adds, "Our vision is to be considered the global market leader of customer satisfaction for contract biopharmaceutical process development and manufacturing services. This facility expansion and successful regulatory inspection represents another step toward making that vision a reality."

About CMC Biologics

CMC Biologics is leading the industry among CMO's 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 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® 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. CMC Biologics' facilities are located in Copenhagen, Denmark; Seattle, Washington; and Berkeley, California. More detailed information can be found at www.cmcbiologics.com.

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