



Press Release

CMC Biologics Enters into Manufacturing Agreement with CytoDyn

Agreement covers process development and manufacture of CytoDyn's PRO 140

Bothell, Washington and Vancouver, Washington, USA– February 15, 2017 – CMC Biologics, a global leader in clinical and commercial manufacturing of monoclonal antibodies, coagulation factors and other therapeutic proteins, and CytoDyn Inc., a biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of Human Immunodeficiency Virus (HIV) infection, announced today they have entered into an agreement for the process development and commercial manufacture of CytoDyn's PRO 140.

PRO 140 is one of the most advanced experimental monoclonal antibodies for HIV treatment and has been used in more than 200 HIV-infected subjects in placebo controlled and open label FDA-approved clinical trials. PRO 140 has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. PRO 140 has been designated a "fast track" product candidate by the FDA. The PRO 140 antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements as compared to daily drug therapies currently in use.

"With limited new drugs in development for treatment of HIV, CytoDyn believes that monoclonal antibodies are poised to become the next class of anti-viral agents on the market for the treatment of HIV. We have selected CMC Biologics based on their successful track record, experience and capacity for scale-up of our mAbs," said Nader Pourhassan, President and CEO of CytoDyn. "Their experience will help us fully develop our downstream processes and enable production of Phase III clinical material, with a keen eye towards process validation and commercial production for PRO 140."

"As HIV continues to be a significant global health issue today, we are pleased to be working with CytoDyn to help fast track this promising new therapy to market," said Gustavo Mahler, PhD, Global Chief Executive Officer & President of CMC Biologics. "Our single-use Bioreactor 6Pack™ facility will allow CytoDyn the flexibility to scale from 2000L up to 12000L in a single production suite. The bioreactors can be run in single unit operations or in groups, simultaneously, sequentially or in staggered fashion to achieve their desired production needs. We very much look forward to working with CytoDyn's team."



About CMC Biologics

CMC Biologics is leading the industry among CMOs 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.cmcbio.com

About CytoDyn Inc.

CytoDyn is a biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV infection. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has completed Phase 2 clinical trials with demonstrated antiviral activity in man and is currently in Phase 3. PRO 140 blocks the HIV co-receptor CCR5 on T cells, which prevents viral entry. Clinical trial results thus far indicate that PRO 140 does not negatively affect the normal immune functions that are mediated by CCR5. Results from seven Phase 1 and Phase 2 human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. A recent Phase 2b clinical trial demonstrated that PRO 140 can prevent viral escape in patients during several months of interruption from conventional drug therapy. CytoDyn intends to continue to develop PRO 140 as a therapeutic anti-viral agent in persons infected with HIV and to pursue non-HIV indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit www.cytodyn.com

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