



Antibody Drug Conjugates

Through their PROVEO™ Partnership, CMC Biologics and IDT Biologika Announce the Addition of Cerbios-Pharma and Oncotec Pharma to their Strategic Collaboration for Manufacture of Antibody Drug Conjugates

Copenhagen (Denmark), Dessau (Germany) and Lugano (Switzerland) –
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CMC Biologics A/S, a global leader in clinical and commercial manufacturing of monoclonal antibodies and other therapeutic proteins, and IDT Biologika GmbH, a privately-held life-science company with a 95 year history of expertise in research, development and manufacture of biologics for human and animal health, announced the addition of Cerbios-Pharma SA (“Cerbios”) and Oncotec Pharma Produktion GmbH (“Oncotec”) to PROVEO, their strategic collaboration for providing a complete and efficient solution to the market for the process development and manufacture of antibody drug conjugates (ADCs).

Within the PROVEO collaborative partnership, CMC Biologics provides monoclonal antibody production, Cerbios performs process development and manufacture of the cytotoxic drug-linker payload, and the conjugation services of the ADC drug substance. Oncotec provides aseptic fill and lyophilization of the ADC drug product, and IDT Biologika performs analytical and quality services, supply chain and secondary packaging through to ready-to-deliver final drug product. These services will be available in early 2017 and will further complete PROVEO’s full ADC service offering.

"We are pleased to join CMC Biologics and IDT Biologika in the development and production of ADCs," said Gabriel Haering, PhD, CEO of Cerbios. "Our extensive experience in the manufacture of cytotoxic drug payloads and conjugation to antibodies will be valuable to clients utilizing the ADC services provided by the PROVEO partnership. Our approved Safebridge Category 4, GMP facility in Lugano was designed to accommodate the complex processes needed for production of very potent active ingredients including cytotoxics like ADCs".

"Cerbios brings two decades of experience working with highly potent cytotoxic compounds and will provide a valuable addition to the ADC services offered by our PROVEO partnership," said Gustavo Mahler, PhD, CEO of CMC Biologics.

Dr. Ralf Pfirmann, CEO of IDT Biologika, added, "We will leverage Cerbios' experience with cytotoxic payloads to round out the ADC services that we offer to our clients. We are also pleased to bring our sister company, Oncotec, into the PROVEO partnership, which will further strengthen the team and provide essential drug product expertise and capacity."

With the addition of these partners, PROVEO now has all necessary competencies, assets and proven experience that are urgently needed by the market for the development and manufacture of complex ADCs, from Drug Substance to Final Drug Product. Additionally, as part of the integrated offering, PROVEO provides Project Management, Supply Chain System, and Quality Systems for its clients.



About CMC Biologics

CMC Biologics is leading the industry among CMOs in customer satisfaction, 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. More detailed information can be found at www.cmcbiologics.com



About Cerbios-Pharma SA

Cerbios is a privately held company located in Lugano, Switzerland, that specializes in the development and manufacture of both chemical and biological APIs for its partners world-wide. Exclusive, third-party manufacturing services are offered by the Chemical Division for HPAs and by the Biological Division for monoclonal antibodies, recombinant proteins and pharma probiotics. Cerbios provides full CMC support to its world-wide partners, including the supply of cGMP clinical batches, registration/validation material and commercially manufactured APIs. Paramount to this is the ability to supply all of the technical documentation and support necessary for a successful registration. Cerbios' commercial products are marketed worldwide but primarily in Europe, USA, Japan and India. More information can be found at www.cerbios.ch



About Oncotec

Oncotec Pharma Produktion GmbH is a reliable worldwide partner for the manufacturing and development of aseptically produced cytostatic drugs. Oncotec specializes in filling of cytostatic liquids and lyophilisates in vials as well as cytostatic liquids in syringes. Since its foundation in 1997, Oncotec has steadily increased

production at our Dessau site. The key to market success is focus on performing manufacturing steps using leading-edge technology production equipment. The state-of-the-art technology and equipment assures that ADC processing is conducted with the highest safety and quality standards. More information can be found at www.oncotecpharma.de

About IDT Biologika

IDT Biologika is an innovative life science company headquartered in Dessau, Germany with extensive expertise in research, development and manufacturing of vaccines, and in addition providing fill, finish and packaging services for antibodies and proteins. It has expanded its longstanding activity in vaccine development for Phase 1 and Phase 2 clinical projects for the human vaccine market through its recently acquired Rockville, Maryland, USA facility. The company also operates vaccine development and manufacturing facilities in Riems, Germany and Cambridge, Canada and sales offices for its own animal health vaccines and biologics product portfolio in Denmark, the Netherlands, France, Spain, China and Canada. IDT Biologika is a company of the Klocke Group. The Klocke Group companies specialize in contract manufacturing and packaging of pharmaceuticals and cosmetic products. Klocke Group also owns a 50 percent stake in Oncotec Pharma Produktion, a cytotoxics development and manufacturing facility, located and integrated in IDT's Dessau site. More information can be found at www.idt-biologika.com.

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