Vetter to Invest €300M In Manufacturing Capacity

IDT Biologika launches U.S. vaccine manufacturing ops

Vetter is investing approximately €300 million to expand and upgrade its manufacturing facilities during the next five years. The company is preparing for future needs and requirements driven by a changing healthcare market that is affected by issues such as more complex molecules, smaller batch sizes, and increasing regulatory requirements.

The first of the facility expansions are underway at several German locations including its 'Ravensburg Vetter West' center for visual inspection and logistics. The facility expansion, which will more than double current capacity, is completed scheduled to become fully operational in 2017. Also, the Ravensburg Vetter South production site and the Ravensburg Schuetzenstrasse facility have been designated for significant expansion, where initial construction activities began in 2013. All three sites will have additional capacities for drug product manufacturing and logistic services.

A central technology element will be implemented with an in-house made improved restricted access barrier system (RABS) concept aimed at increasing operational excellence in aseptic manufacturing. To better meet future industry trends in quality, safety and flexibility, a corporate project team has evolved this 'Improved RABS concept' by combining the advantages of isolator and RABS technology.

This approach, according to the company, results in a uniquely fast, 3-hour cycle and fully automated decontamination of the cleanroom using hydrogen peroxide (H2O2), with an extremely high level of process innovation. Following a successful pilot project, the company will now implement this decontamination concept in all of its cleanrooms within the next few years.

"We are continuously monitoring and reacting to a changing marketplace and are pleased that we are in the position to be able to make these strategic investments to further develop our sites and meet these challenges. Individually and collectively, they will help us keep pace with the market and allow us to continue to build a successful future for Vetter and our customers," said Vetter managing director Peter Soelkner.

IDT Biologika Launches U.S. Vaccine Mfg. Ops

IDT Biologika has dedicated its first U.S. vaccine manufacturing facility in Rockville, MD. The new facility provides a bridge between preclinical development and Phase II clinical trials with capabilities including, process development, cell banking, cGMP manufacturing, purification and formulation, and fill and finish.

The facility is BSL-2 compliant and meets both U.S. FDA and European Medicines Agency (EMA) standards. IDT shares the 75,000-sq.-ft. building with Aeras, a nonprofit, global biotech organization developing new tuberculosis vaccines, and is partnering with Aeras on process development and manufacturing of tuberculosis vaccine candidates.

"The Rockville facility marks a milestone for IDT Biologika as we expand our worldwide operations into the United States and continue our commitment to meet the vaccine development and production needs in key markets," said IDT Biologika president Dr. Ralf Pfirmann. "With the new facility, we provide U.S. companies with a highly capable and experienced CMO-partner for phase I and phase II clinical vaccine projects right from the heart of the BioMaryland corridor."

Amgen Acquires Dezima Pharma

Amgen has acquired Dezima Pharma, a biotechnology company developing drugs to treat cardiovascular disease from Forbion Capital for as much as $1.6 billion.

Dezima was founded in 2012 by Prof. John Kastelein, Professor of Medicine at the Department of Vascular Medicine at the Academic Medical Center of the University of Amsterdam, The Netherlands. Amgen gains its TA-8995 oral, once-daily CETP inhibitor in development for use in patients with mild dyslipidemia. TA-8995, both as monotherapy and on top of statins, caused significant decrease of LDL and simultaneous increase of cholesterol efflux capacity.

Sander Slootweg, Forbion's managing partner and chairman of Dezima, said, "Dezima is the poster child of a successful modern start-up company. Several of our team and advisors, including Prof. John Kastelein, filled critical management positions, such as interim chief executive officer, chief financial officer and project management. Xention Ltd, one of our UK portfolio companies, designed and executed the required pre-clinical studies and optimized the manufacturing of the product." Mr. Slootweg added, "Today's acquisition and the value that Amgen has set on the company, validates our belief in the team and the science. Dezima will be a great fit for Amgen and complements its other products targeting high cholesterol."

"There has been an auspicious coming together of key elements leading up to this acquisition: the combination of great chemistry by MTPC which designed TA-8995, our skilled preclinical and clinical development team led by Dr. John Ford and Dr. Patrick Round in Cambridge (UK) coupled with smart capital provided by Forbion, NSV and BGV," said John Kastelein, chief scientific officer and founder of Dezima. "I am proud to be part of this exceptional team and company, and I look forward to working with Amgen to speed this highly promising product to market." CP