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Interview

Abivax CEO Hartmut Ehrlich on what's needed to establish new approaches to autoimmune diseases.

Protein Degraders

Molecular Targeting

Industrial Biotech

Bioengineered bacteria that could help stop climate change

Patent Waiver

How the WTO is corroding the roots of biopharma innovation

CROs & CDMOs

How gene and cell therapies are transforming the pharma market

BIOCOM

Vital expertise in virotherapy manufacturing

We recently completed a major milestone in its $50M Cuxhaven facility expansion with a new 500 L manufacturing line. The site provides services for clients with preclinical through Phase I-II oncolytic virus, viral vector gene therapy, and vaccine programs, across global regulatory filings.

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Bringing virotherapy forward

VIRAL VECTORS Whether it´s oncogenic viruses or vectors for cancer therapy or modern vaccines, the demand for development, production or filling capacities is rising rapidly. To keep pace with this rise in customer demand, Vibalogics, which recently became part of the Recipharm Group, is investing around US$50m in the expansion of its Cuxhaven site by the end of the year, and even more in the US site near Boston.

› Stefan Beyer, President & Managing Director, Vibalogics, a Recipharm Group company

Vibalogics, one of the world's leading CDMOs for the supply of viral vectors, is expanding its services in cancer immunotherapy with oncolytic viruses and viral vectors for vaccines both in Europe and the USA. The company, which became part of Recipharm Group last year, helps customers develop and manufacture oncolytic viruses that open up promising possibilities for cancer immunotherapy. The natural properties of the virus to multiply in cancer cells in particular and to lyse them can be enhanced many times over by use of recombinantly integrated immunostimulatory factors or the combined administration with immunomodulatory factors.

Shortly after its foundation in 2002 in Cuxhaven, Germany, Vibalogics' focus was on providing oncolytic viruses for customers in Europe and North America. Several production platforms have been established since then. The development of manufacturing processes using different cell substrates for the propagation of enveloped and non-enveloped DNA and RNA viruses are part of the offering. GMP clean rooms of classes A,B,C and D allow us a completely aseptically managed production, which in many cases allows the use of cell substrates growing in suspension as well as adherently.

In Cuxhaven, manufacturing processes are developed for the provision of oncolytic viruses to subsequently produce test material for clinical trials by GMP standards. Two lines with 200 or 500 litre volumes are available, as well as two production suites for the production of viruses for aseptic vector production on adherently growing cell substrates. There is also a filling line with a capacity of more than 25,000 units per batch.

Vibalogics virotherapy manufacturing facility in Boxborough

What began with the establishment of a modern, virus-specialised filling plant for the finished products, and continued with the expansion of bioreactor capacities, was again accelerated from May 2019 onwards following the acquisition by the American growth-oriented investor Ampersand Capital Partners. The strategy proposed by Vibalogics to expand the site in Cuxhaven, but in particular the establishment of a second site with significantly larger capacities in the USA to better serve North American customers, has been consistently implemented over the past three years. With the establishment of the facility in Boxborough/Boston, Massachusetts, USA, the Vibalogics headquarters also moved. Together with Cuxhaven, Vibalogics now covers the entire value chain for the production of oncolytic viruses, viral vectors for gene therapy and virus vector-based vaccines for clinical trial phases and approved market products.

Expansion in three phases

In Cuxhaven, this is a three-phase expansion. With the first phase, an additional building was constructed and the capacity for viruses growing on suspension cells was more than doubled. The new facility consists of two rooms for growing the cell substrate and one room each for the so-called upstream and downstream processes (USP, DSP). The facility is equipped with state-of-the-art control and monitoring systems especially for the production of viral vectors up to biological safety level 2. Customers particularly like the ability to follow USP and DSP production via large window areas.

Vibalogics Cuxhaven now operates two complete lines for the production of oncolytic viruses, whereby the customer can choose between two different single-use bioreactor platforms (SUB). It is easy to switch between the two systems using tech transfer and available standard operating procedures. With the new 500L line, Vibalogics also offers customers smooth 1:1 tech transfers "at scale" between the two sites in Cuxhaven and the USA. The technical systems are the same, and the employees are trained on the same tech-

nical systems and work instructions. Standard operational procedures and a quality management system rolled out across both sites, which is currently being supplemented or replaced by the implementation of an electronic system, allowing Vibalogics' customers to freely choose whether the manufacture of their product is to be monitored by the FDA or EMA. This applies to both the so-called drug substance and the sterile-filled end product for clinical testing. Both sites operate the appropriate qualified filling facilities.

In addition to the expansion of GMP manufacturing capacity for suspension-based cell substrates, both process development and quality control have been equipped with additional systems.

Vibalogics offers its customers additional capacity, more flexibility and agility at both sites to provide viral vectors for cancer and gene therapy as well as for preventive and therapeutic vaccination in a more timely manner.

Phase 2 will take approximately additional approximately 550 m2 of laboratory space for quality control and process development by the end of 2022, after Vibalogics took ownership of the entire building complex in August.

Phase 3, which will follow shortly after, will increase infrastructure capacity to accommodate more than 200 employees by the end of 2023, create additional storage capacity, material preparation and post-processing areas, and build further redundancies of critical systems. This will further expand the overall capacities.

In phases 2 and 3, attention will also be paid to very close cooperation between the two sites. Training the staff of both locations on the same systems offers the customers flexibility, but above all also risk minimisation in case of short-term additional staff requirements. A joint warehouse and logistics system increases the ability to deliver in times of uncertain supply chains.

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Growing within Recipharm

In April 2022, Vibalogics was acquired by the Swedish Recipharm Group, which, as a global CDMO with more than 9,000 employees in more than 30 locations worldwide, will form the advanced therapy medicines (ATMP) service area together with the companies Arranta Bio (USA) and Genibet (Portugal). This will open up synergies that will allow Vibalogics to serve its customers better and more sustainably on a global basis in the future. From now on, clients will be offered a very broad range of services, allowing them to develop and commercialise microbiotic as well as viral and nucleic acid-based products under one roof. ■