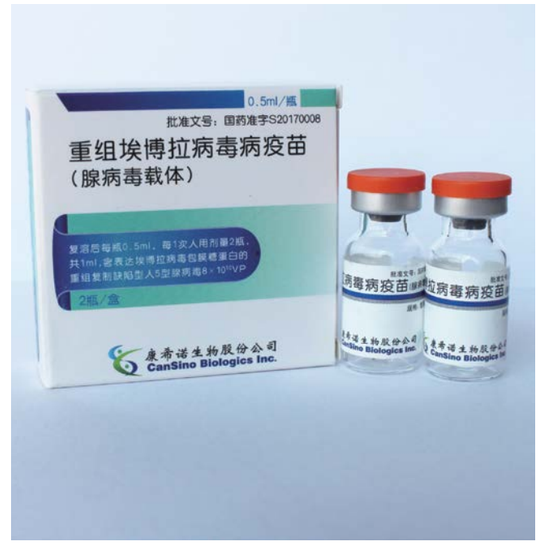
A best shot at global public health response

From tuberculosis and pneumonia, to Ebola and Zika, a Chinese biotech firm is DEVELOPING HIGH-QUALITY VACCINES to address global health challenges.



In 2017, China's food and drug authority approved its first Ebola virus vaccine, making China only the second country to licence a vaccine for this deadly disease. Causing a sudden onset of high fever, followed by vomiting, diarrhoea, and internal and external bleeding, Ebola, with mortality rates varying from 40% to 90%, has no proven treatment so far. The outbreak of Ebola virus in West Africa in 2014-16 killed more than 11,000 people. Vaccination is vital for disease control. A recombinant Ebola virus vaccine, jointly developed by Beijing Institute of Biotechnology and CanSino Biologics Inc. (CanSinoBIO), a Tianjin-based company specialising in the development and manufacture of human vaccines, offers a new tool for combating this devastating threat to public health.

The Ad5-EBOV vaccine developed in China relies on the recombinant replication-defective human adenovirus type-5 vector to induce immune responses and provide protection against the Ebola virus. Manufactured as a lyophilized powder, it is highly stable and does not require storage at ultra-low temperatures. This feature renders it viable for use in resource-limited tropical areas. Such ease of storage and handling gives the Ad5-EBOV vaccine an edge over competing products from multinational pharmaceutical companies. With recent reports of new Ebola outbreaks in Democratic Republic of the Congo, the Ad5-EBOV vaccine, already approved in China for emergency use, could be included in international emergency vaccine stockpiles.

Yu Xuefeng, chairman and CEO of CanSinoBIO, points out that from a concept to an approved product, the development of Ad5-EBOV vaccine took just a little more than three years, demonstrating CanSinoBIO's strong capability for efficiently pushing a candidate through R&D and completing pre-clinical studies and clinical trials. With advanced R&D platforms, cutting-edge technologies and an efficient management system, the company boasts a proven track record of success in new drug discovery, development and commercialization. "We want to lead and foster the Chinese vaccine industry to become a major contributor to global public health," says Yu.

Diversified vaccine products

Founded in 2009 by four Chinese returnees, who held senior management and technical positions at world-renowned pharmaceutical companies abroad, CanSinoBIO has now developed into a team of more than 300 professional R&D, commercial and manufacturing staff, who are on a quest to develop affordable, high-quality and innovative vaccines for people in China and around the world. Its expertise lies in antigen discovery, efficient CMC development, and a world-standard quality system, manufacturing system and management team. The company has been able to push multiple vaccine candidates through proof-of-concept pre-clinical evaluation and human phase 1 through phase 3 clinical trials.

In view of the growing Chinese demand for vaccines, CanSinoBIO focuses on three major product lines. The Ebola vaccine, along with the adenovirus-based recombinant TB vaccine and the protein-based pneumococcal vaccine (PBPV), represent innovative vaccine products. For instance, in using pneumococcal proteins or virulence factors to reduce the virulence of infecting bacteria, PBPV is seen as next-generation technology for pneumococcal vaccines. It provides an alternative to the conventional serotype-based conjugate vaccines that only cover limited number of serotypes. PBPV may also provide broader protection. With an anticipated simplified production process and lower cost compared with current conjugate vaccines, efforts are underway to translate success in animal models to human vaccines. CanSinoBIO has now completed pre-clinical studies for its PBPV product, which is intended for use for all ages, and obtained approval for conducting clinical trials from the Chinese regulatory authority. Its TB vaccine is already undergoing clinical trials in Canada.

Another line of products is first-in-class vaccines not currently available in China. The company developed these vaccines utilizing its core technologies, which significantly improve the current vaccines in use globally. Examples include the quadrivalent (ACYW135) meningococcal conjugate vaccine (MCV4) for protection against infection from four types of meningococcal bacteria, as well as DTcP-based combo vaccines. Both of these vaccines are in high demand in China. CanSinoBIO now completed the phase III clinical trials for MCV4 and has initiated clinical trials for DTcP.

CanSinoBIO is also determined to develop its own vaccines to compete with imported products. Pneumococcal conjugate vaccines (PCV13i) are currently in development. The pre-clinical studies have been already completed. "We are aiming at developing best-in-class vaccines in China for the world," said Yu.

The company currently has 15 vaccine products in the pipeline, covering 12 disease areas. Among these, six are still in pre-clinical stage, including vaccine candidates for adenovirus, meningitis, shingles, polio, and Zika virus. It will further optimise its product pipelines to better meet market demand.

Advanced technological platforms

With great lab and human resources for microbiology, molecular cell biology, immunology and biochemistry, CanSinoBIO has developed advanced technologies to support its strong product pipeline. The adenovirus-based viral vector vaccine technology, used for R&D of the Ebola vaccine, is a preferred strategy for preventing emerging infectious diseases. It also enables CanSinoBIO to develop its TB booster and other vaccine candidates.

The conjugation technology platform allows CanSinoBIO to manufacture a wide range of conjugate vaccines. With various carrier proteins, including the commonly used DT and TT carrier proteins, and CRM197, CanSinoBIO has developed high-quality multi-valent conjugate and combination vaccines, standing out among its Chinese competitors. Its PCV13, potentially a best-in-class in China, employs a combination of different carrier proteins and is ready for clinical trial application.

With protein structure design and recombinant technology, CanSinoBIO has designed pneumococcal protein antigens and engineered novel recombinant strains for a new pertussis vaccine with significantly high yields. The technology is also applied to developing proprietary cell lines for viral vector production.

The formulation platform ensures consistent quality and reduces potential risk of side effects. CanSinoBIO has formulations free from any animal components, phenol and preservatives.

The company is also equipped with state-of-the-art animal research facilities and has built pilot and commercial manufacturing facilities to meet international standards. "Vaccination is an essential part of effective disease control and prevention," says Yu. "Our ultimate goal is to make high-quality vaccines accessible to people all over the world."

To achieve its ambition, CanSinoBIO plans to raise more capital through an IPO on the Hong Kong stock exchange. It is also actively recruiting talent worldwide, seeking people with expertise in R&D, quality control, manufacturing, commercial operation, and more. ■

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