

BioRay Biopharmaceuticals' Adalimumab Biosimilar Approved for Marketing in Pakistan

On December 12, BioRay Biopharmaceutical Co., Ltd. (hereinafter referred to as BioRay) announced that its adalimumab biosimilar, developed in-house by its wholly-owned subsidiary Hisun Biopharmaceutical Co., Ltd., and registered in Pakistan by its local partner Searle, was successfully approved for marketing by Drug Regulatory Authority of Pakistan, making it the first adalimumab product in the country.

According to the license agreement between BioRay and Pakistani pharmaceutical company Searle, Searle will be responsible for the local commercialization of adalimumab biosimilar (Chinese Trade Name: Anjianning®) in Pakistan. This cooperation will further address the unmet clinical needs for patients, accelerate the expansion of the global footprint of BioRay's adalimumab and help more patients around the world receive high-quality treatment.



Anjianning®, was first approved in China in 2019. It is an all-human monoclonal antibody against tumor necrosis factor α (TNF- α), which can selectively bind to TNF- α molecules and prevent them from adhering to healthy cells, thus reducing the damage caused by excessive TNF- α . A total of 648 patients were included in the Phase III clinical study of Anjianning®, which is the Phase III clinical study with the largest sample size among similar products in China. The efficacy and safety were fully verified, and the research results were published in the SCI journal (impact factor: 5.31). At present, the approved indications of Anjianning® including rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, psoriasis, pediatric plaque psoriasis, Crohn's disease, pediatric Crohn's disease and non-infectious uveitis.

Dr. Haibin Wang, CEO of BioRay, said: "The friendship between China and Pakistan has been close and long-lasting. We hope our further cooperation with Searle will cement the company's market position in related medical therapy fields internationally and accelerate the wider accessibility of Anjianning® on a global scale. At present, BioRay products have been under registration in more than 20 countries and regions, and we are actively working with local partners toward improving the quality of life of local patients."

Dr. Syed Nadeem Ahmed, PH.D. Group Managing Director & CEO of Searle Company Limited., said: "Partnership with BioRay is an integral part of our strategy to develop further our biotechnology business in Pakistan. The goal of this project is not only to bring BioRay products to Pakistan, but also to establish cooperation with such an innovative company as BioRay. This cooperation also represents an important milestone for The Searle Co Ltd., and for our patients in



Pakistan that will ensure the social benefit from increased access to high-quality affordable medicines”.

ABOUT BIORAY

BioRay is a pioneer in China’s biopharmaceutical industry focusing on immune-mediated diseases. Its extensive autoimmune and oncology portfolio includes six marketed products and over 10 clinical-stage drug candidates. Operating a fully integrated platform with end-to-end capabilities across drug discovery, clinical development, manufacturing, and commercialization, BioRay has over 1,700 employees globally, with main sites in Taizhou, Hangzhou, Shanghai, and San Diego.

For more information about BioRay, please visit the company website: www.bioraypharm.com/en/

ABOUT SEARLE

The Searle Company Limited (TSCL) was established in Pakistan as a Private Limited Company on October 5, 1965 as a subsidiary of G.D. Searle & Co., USA. TSCL has been in pharmaceutical business for more than 55 years and is one of the top pharmaceutical companies in Pakistan having Eight state-of-the art manufacturing facilities and global presence in more than 20 countries. Today, Searle is among the top three companies of Pakistan in terms of revenue, and consistent high growth. TSCL have more than 4000 employees, including a dedicated sales force that visits doctors, pharmacists, retail outlets, hospitals, and wholesalers to promote the company's products.

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