

Samsung Bioepis continues global expansion

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Enters Brazilian Biopharmaceutical Market with BRENZYS



Korean firm Samsung Bioepis Co., Ltd. has announced its expansion into the Brazilian biopharmaceutical market. The first product available in the country is BRENZYS™ (etanercept), a biosimilar referencing ENBREL®.

BRENZYS™ was approved by Agência Nacional de Vigilância Sanitária (ANVISA), the country's health regulatory agency, in December 2017 for the treatment of rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, and non-radiographic axial spondyloarthritis.

Samsung Bioepis is continuing its business expansion in multiple markets across the world, including mainland China, where the company entered into partnerships with 3SBio and C-Bridge Capital to develop and commercialize multiple biosimilar candidates from Samsung Bioepis.

BRENZYS™ is being supplied to Sistema Único de Saúde (SUS), the country's public health system, through a Productive Development Partnership (PDP) between Samsung Bioepis and local partners, Bionovis and Bio-Manguinhos/Fiocruz.

Under the PDP, Samsung Bioepis will supply biosimilar products or product intermediaries to the local partners for sale to SUS for a period of 10 years. During this period, Samsung Bioepis will provide technology transfer to the local partners, so that manufacturing responsibilities can be gradually transferred to enable local manufacturing in Brazil. The PDP scheme was introduced by the Brazilian government in 2008, in order to expand access to medicines and support the country's pharmaceutical industry through technology transfer from established companies in return for guaranteed purchases from SUS.

In Brazil, over 75% of patients nationwide rely on SUS for health care coverage. While biologics represent approximately 4% of all medicinal products acquired by SUS, they account for approximately 51% of government spending on medicinal products.