

Third U.S. biosimilar nod offers good news for Samsung Bioepis, though sales delayed – for now

By Jihyun Kim, Staff Writer

Samsung Bioepis Co. Ltd.'s recent FDA approval to market biosimilar Eticovo (etanercept-ykro) in the U.S., marking another significant step forward for the growing South Korean drugmaker, may not bring any real benefits for almost a decade. But the U.S. nod sets the stage for Bioepis to potentially nab a significant share of the etanercept biosimilar market in the future.

For the time being, any potential gains in the U.S. are theoretical. The patent covering the original anti-TNF treatment, marketed by Amgen Inc. as Enbrel, remains in place and is not expected to expire until November 2028. As of now, Samsung Bioepis has not confirmed a launch schedule or a distributor. According to the FDA, a biosimilar can be produced when the original product's patent expires.

Etanercept is indicated for autoimmune diseases including rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis and polyarticular juvenile idiopathic arthritis. Global sales of the drug reached nearly \$7.13 billion in 2018 and ranked sixth among the top 15 pharmaceutical products, according to Statista.

"There will be many competitor products when Eticovo starts launching in the U.S. market after 2028. To succeed in the U.S., the company should focus on marketing, especially by raising recognition of the biosimilar product among big hospitals and doctors," Jaecheon Yeo, executive director of the Korea Drug Research Association, told *BioWorld*.

Samsung Bioepis, part of the South Korean conglomerate Samsung Group, expects to take a big portion of the market, as sales of Enbrel in the U.S. accounted for 67% of the global market in 2018.

So far, it has done well in capturing a share of the biosimilar etanercept market in other areas.

In 2016, Samsung Bioepis received European Commission approval to market Benepali, as the etanercept biosimilar is branded in Europe. Accumulated sales for the first three quarters in the European market reached \$389.1 million.

According to market research company Iqvia, sales of Benepali accounted for 40% of the etanercept market in Europe as of February. And its sales volume is five times larger than that of rival biosimilar Erelzi, from Sandoz Pharmaceutical Co. Ltd., a subsidiary of Basel, Switzerland-based Novartis AG.

The product has been approved for marketing in 38 countries overall, also including Canada, Australia, New Zealand and Israel.

It's the third biosimilar Bioepis is ready to place in the U.S. market. To date, the Korean biotech has launched Renflexis (infliximab biosimilar) in the U.S., partnering with Merck & Co. Inc. in July 2017. Merck inked an exclusive contract last October to supply Renflexis with U.S. Department of Veterans Affairs for five years.

Samsung Bioepis also won FDA approval for Ontruzant (trastuzumab biosimilar) in January. Other biosimilar products include Humira (adalimumab biosimilar), for which the FDA accepted a filing in September, and biosimilar versions of bevacizumab, ranibizumab and eculizumab, which are undergoing clinical trials.

Besides its business in the U.S. and Europe, Samsung Bioepis' recent licensing agreement with China's 3Sbio Inc. will expand its biosimilar business to the Chinese mainland. (See *BioWorld*, Jan. 8, 2019.)

Dealing with trouble at home

Samsung Bioepis, which along with Celltrion Inc., has emerged as one of the two biggest Korean players in the biosimilar space. But while its drug development program continues to expand, Samsung Bioepis is also working to overcome difficulties at home.

The company has been embroiled in an accounting scandal since May 2018. Two Samsung Bioepis employees were arrested last month on suspicion of falsifying and destroying evidence to cover up an alleged SKW4.5 trillion (US\$3.87 billion) accounting fraud a year earlier.

The Financial Services Commission, the Korean government's financial supervisory agency, ruled in November that Samsung Biologics Co. Ltd. deliberately inflated the value of its stake in Samsung Bioepis to boost the value of Samsung Biologics shares (KRX:207940) in violation of Korea's audit law.

Samsung Bioepis was founded by Samsung Biologics and Biogen Inc., a U.S.-based biopharmaceutical company, in 2012. The two held stakes of 85% and 15%. However, last year, Samsung Biologics ceded part of its stake to Biogen, lowering its holdings in the biosimilar maker to 43%.

"Until the final decree closing the case, the company's stock price may vary with uncertainty. However, the scandal would not seriously affect the company's global business of biosimilar products as the case is not related to the biopharmaceutical product itself," Hyungsoo Kim, an analyst at Cape Investment & Securities Co. Ltd., told *BioWorld*.

Still, the company has to deal with a competitive market, which for Enbrel, in particular, has been heightened by the patent trial between Amgen and Sandoz since 2016.

According to a report in March by SVB Leerink LLC, Amgen has licensed two patents from Roche Holding AG that give it market exclusivity to 2028-29. Sandoz is contesting those patents. Sandoz received an FDA approval for Erelzi in 2016 and filed an initial complaint to invalidate the existing patents. (See *BioWorld Today*, Aug. 31, 2019.)

The investment bank's report said if Sandoz prevails, the U.S. launch of the Enbrel biosimilar could happen as early as 2021. A U.S. District Court decision is expected mid-2019, and a subsequent appeal 12 to 13 months later in 2020. If Amgen wins, the company would secure its U.S. Enbrel market until 2029.

Shares of Samsung Biologics fell 0.89% on Friday to SKW334,000. Last year, the stock slumped from SKW556,000 at the end of September to SKW281,000, its lowest point, in early November. ♦