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Singapore: Korean drug giant Samsung Bioepis, recently revealed that it is seeking regulatory approval in Europe to sell its copy of AbbVie Inc's rheumatoid arthritis drug Humira. The company, in its press release, said that the European Medicines Agency (EMA) has accepted for review the company's Marketing Authorization Application (MAA) for SB5, a biosimilar candidate referencing Humira® (adalimumab).

The Marketing Authorization Application for SB5 was based on a 52-week Phase III study which showed SB5's comparable efficacy and safety to Humira among different treatment groups, including those who switched from Humira to SB5. If approved, SB5, a biosimilar candidate referencing Humira (adalimumab), will be Samsung Bioepis' third anti-TNF-Î± biosimilar in Europe.

As per reports, Humira is one among the world's best-selling drug that generated $14 billion in sales last year. "If approved, SB5 will join Benepali and Flixabi in Europe, which have already started to increase patient access to high-quality treatment options while driving down healthcare spending," said Christopher Hansung Ko, President & CEO of Samsung Bioepis."We will continue to work hard to advance one of the industry's largest biosimilar pipelines, so that more patients can access affordable medicines without any compromise in the quality of treatment."

With 13 biosimilar candioddates under development,Samsung hopes to ride high in the biosimilar wave in Asia. The company aims to make its biosimilar division a new growth driver as the global smartphone industry matures, clouding long-term

earnings prospects for flagship Samsung Electronics.

Samsung said that if approved, the marketing and distribution of SB5 in Europe will be handled by Biogen. Samsung Bioepis, which seeks to be first or second to market with its products, already received regulatory approval earlier this year to sell its copies of Amgen Inc's Enbrel and Johnson & Johnson's Remicade - two rheumatoid arthritis drugs that are also among the world's best-selling medicines.