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Singapore: European Medicines Agency (EMA) has nodded to review the marketing authorization application (MAA) of Enbrel (etanercept) biosimilar candidate, SB4, developed by Korean biopharmaeutical firm, Samsung Bioepis.

Acceptance of the MAA marks the first Enbrel biosimilar to advance into regulatory review in the European Union (EU). The MAA is based on results from a Phase III clinical trial in patients with moderate-to-severe rheumatoid arthritis (RA).

In Europe, Enbrel is indicated for the treatment of a number of rheumatic diseases, including moderate to severe RA, certain forms of juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. If authorized by the EMA, SB4 could be available for use in all of the same indications as Enbrel.

"This MAA validation represents a significant milestone for Samsung Bioepis in our work to develop and manufacture world-class biosimilars. More significantly, it offers an opportunity to provide high-quality and effective therapies for broadening access to patients in Europe," said Mr Christopher Hansung Ko, chief executive officer, Samsung Bioepis.

If authorized by the EMA, SB4 will be commercialized in Europe by Biogen Idec. It will also be produced at the company's manufacturing facility in Denmark which is one of the largest biologic manufacturing facilities in the world.

In addition to the European filings, Samsung Bioepis intends to move forward with additional applications for regulatory approvals in other territories worldwide.