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# Samsung JV seeks second biosimilar approval in Europe

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**Samsung JV seeks biosimilar approval in Europe**

**Singapore:** Samsung Bioepis, a joint venture between Samsung Biologics and Biogen Idec, has submitted marketing authorization application (MAA) for SB2, its Remicade (Infliximab) biosimilar candidate, to European Medicines Agency (EMA).

This is the second biosimilar candidate MAA that Samsung Bioepis has submitted to the EMA.

The MAA is based on results from an extensive head-to-head preclinical data package comparing SB2 to the originator, a head-to-head Phase I study in healthy volunteers, and a robust head-to-head Phase III equivalence trial in patients with moderate-to-severe rheumatoid arthritis (RA). In Europe, Remicade is indicated for the treatment of rheumatic arthritis, adult Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, psoriatic arthritis, ankylosing spondylitis and psoriasis. If authorized by the EMA, SB2 could be available for use in all of the same indications as Remicade.

"If this MAA is approved by EMA, Samsung Bioepis will provide rheumatoid arthritis patients in Europe with an important new treatment option," said Mr Christopher Hansung Ko, chief executive officer, Samsung Bioepis. If authorized by the EMA, SB2 will be commercialized in Europe by Biogen Idec.

In addition to the European filing for SB2, Samsung Bioepis previously announced that the EMA had accepted an MAA for SB4, its Enbrel (etanercept) biosimilar candidate, which is currently under regulatory review. The company intends to move forward with additional applications for regulatory approvals in other territories around the globe.