

Samsung progresses on RA biosimilar drug ph 3 trial

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Singapore: Korea pharma giant, Samsung Bioepis, has successfully completed Phase 3 clinical study of SB5, an investigational biosimilar of Humira (adalimumab) for treating rheumatoid arthritis.

SB5 is being developed as a biosimilar to adalimumab, an anti-TNF- α monoclonal antibody, which is approved in many countries for the treatment of autoimmune diseases, including rheumatoid arthritis, plaque psoriasis (PsO), psoriatic arthritis, ankylosing spondylitis, Crohn's disease and ulcerative colitis. The active ingredient of SB5 has the same amino acid sequence as adalimumab, and SB5 has the same pharmaceutical dosage form and strength as adalimumab (US) and adalimumab (EU)

"We have developed SB5 following SB4 and SB2. Now we have developed biosimilars for three of the best-selling biologics for autoimmune disease," said Dr Christopher Hansung Ko, chief executive officer, Samsung Bioepis. "We look forward to providing increased access to patients suffering from autoimmune diseases within the same healthcare budget, and consequently bend the curve of rising healthcare costs worldwide"

Samsung Bioepis has been developing six biosimilar molecules and expects to launch those products starting in 2016. Marketing authorization application for SB2 and SB4 have been submitted to health authorities in the EU and South Korea. Additional biosimilars in development by the South Korean company, are SB9 -an insulin glargine biosimilar candidate, which is currently in phase 3 clinical studies, SB3 -an investigational biosimilar of Herceptin, also in phase 3, and SB8 - an

investigational biosimilar of Avastin, which is currently in phase 1 clinical studies.