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29 November 2016 | News | By BioSpectrum Bureau

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Singapore: Clinical trials for new Rituxan biosimilar has been initiated by a joint venture between Samsung Biologics and AstraZeneca- Archigen Biotech. According to the Korean Ministry of Food and Drug Safety, Archigen's SAIT101 was granted approval to begin phase 1 and phase 3 clinical trials at eight local hospitals on Nov. 11. The trials in Korea are currently ongoing, the Samsung unit said.

In addition to Korea, Archigen Biotech has been conducting clinical trials of SAIT101 in the US since July, according to Samsung BioLogics. The company further said that on completion of clinical trials, AstraZeneca is set to take charge of SAIT101's marketing and sales in the US.

Biosimilars refer to cheaper, near-replicas of biologic drugs which have lost patent protection. SAIT101 is a biosimilar referencing Rituxan, a lymphatic cancer treatment which generated $7.3 billion in annual sales last year as the world's second best-selling biologic drug.

Unlike newly developed drugs which are required to complete phase 1, 2 and 3 clinical trials before they can be submitted for approval, biosimilars are generally mandated to undergo only phase 1 and phase 3 trials.

Apart from this, many other Korean companies are jumping into the booming sector of biosimilars. Korea's Celltrion's Truxima scored sales approval in Korea for the treatment of Non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid

arthritis.

In addition, Novartis-owned Sandoz submitted its own Rituxan biosimilar to the EMA for approval in May this year. Pfizer and Amgen are wrapping up third-phase clinical trials of their own Rituxan biosimilars as well.