
Samsung Bioepis starts phase 1 clinical trial of new pipeline'SB16'

-Full-fledged development of skeletal disease treatments with annual global sales of KRW 3 trillion-
Confirmation of drug safety and immunogenicity, etc. for 168 healthy adult males-
Secured the 9th biosimilar pipeline... Accelerating portfolio diversification strategy

Samsung Bioepis (CEO: Han-Seung Ko) selected skeletal disease treatment'SB16 (Prolia biosimilar, ingredient name denosumab)' as a new biosimilar pipeline, and started to develop full-scale. Phase 1 clinical trials have begun.

According to the content posted on the global clinical trial information website'clinical trials.gov' on November 9th, Samsung Bioepis has been providing drugs for healthy volunteers in France from October 2020. A phase 1 clinical trial was initiated to confirm kinetics (PK/PD), safety, and immunogenicity.

* [Reference] Website address: <https://clinicaltrials.gov/ct2/show/NCT04621318>

Profile Oh Raleigh (Provia®) US Amgen (Amgen) as a skeletal disorder osteoporosis drugs have developed bone cancer and sseuyimyeyo a loss drugs, such as last year's global sales of about 3.1 trillion won (2.6 billion 7,200 million)¹⁾ in Reach.

An official of Samsung Bioepis said, "Through the clinical launch of our 9th biosimilar pipeline 'SB16', we have taken the first step in the development of a new antibody treatment, and will continue to expand our diverse product portfolio." He said.

Samsung Bioepis is currently selling 3 types of autoimmune disease treatments (SB2, SB4, SB5) and 2 types of tumor disease treatments (SB3, SB8). have. In addition, in order to expand the biopharmaceutical portfolio to various treatment areas, the company is spurring the development of subsequent biosimilars such as eye disease treatment (SB11, SB15) and blood disease treatment (SB12).²⁾

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[Footnote description]

1) The dollar-won exchange rate applies the KRW-dollar trading standard rate (KRW 1,156.00) at the end of 2019

* Source: KEB Hana Bank FX Portal

<https://www.kebhana.com/cont/mall/mall15/mall1501/index.jsp>

2) Samsung Bioepis pipeline status (as of November 2020)

프로젝트 명	제 품 명			오리지널 의약품	구 분	개발 단계
	한국	유럽	미국			
SB4	에톨로체 (Etolocet TM)	베네패리 (Benepali TM)	에티코보 (Eticovo TM)	엔브렐 (Enbrel [®])	자가면역질환 (류마티스 관절염 외)	판매허가 (KR, US, EU 외)
SB2	레마로체 (Remalocet TM)	플릭사비 (Flixabi TM)	렌플렉시스 (Renflexis TM)	레미케이드 (Remicade [®])		판매허가 (KR, US, EU 외)
SB5	아달로체 (Adalocet TM)	임랄디 (Imraldi TM)	하드리마 (Hadlima TM)	휴미라 (Humira [®])		판매허가 (KR, US, EU 외)
SB3	삼페넛 (Samfenet TM)	온트루잔트 (Ontruzant TM)	온트루잔트 (Ontruzant TM)	허셉틴 (Herceptin [®])	종양질환 (유방암 외)	판매허가 (KR, US, EU 외)
SB8	-	에이빈시오 (Avbintio TM)	-	아바스틴 (Avastin [®])	종양질환 (대장암, 폐암 외)	판매허가(EU) 심사 중(US)
SB11	-	-	-	루센티스 (Lucentis [®])	안과질환 (황반변성 외)	심사 중(EU)
SB12	-	-	-	솔리리스 (Soliris [®])	혈액질환 (PNH 외)	임상3상 진행 중
SB15	-	-	-	아일리아 (Eylea [®])	안과질환 (황반변성 외)	임상3상 진행 중
SB16	-	-	-	프롤리아 (Prolia [®])	골격계질환 (골다공증 외)	임상1상 진행 중