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ASIA EDITION

Samsung Bioepis announces launch of Denosumab Biosimilars, OBODENCE™ and XBRYK™, in Europe

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South Korea-based Samsung Bioepis Co. has announced the launch of OBODENCE™ (60 mg pre-filled syringe) and XBRYK™ (120 mg vial), denosumab biosimilars referencing Prolia and Xgeva. The products will be commercially available in Europe in December 2025 and January 2026, respectively.

OBODENCE, referencing Prolia, has been approved for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures, and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.

XBRYK, referencing Xgeva, has been approved for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone, and treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

OBODENCE, the company's first biosimilar in endocrinology, and XBRYK, the company's third biosimilar in oncology, mark Samsung Bioepis' 10^{th} and 11^{th} biosimilars available in Europe. They add to the company's diverse therapeutic portfolio ranging from immunology, oncology, ophthalmology, hematology, and nephrology.