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Mabwell secures Pakistan's first Denosumab injection approval

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Expanding the product's commercialisation to additional countries, thereby improving global accessibility to denosumab injections

Mabwell, a China-based biopharmaceutical company, and Pakistan's The Searle Company have jointly announced that two denosumab products, 9MW0311 and 9MW0321, have received marketing authorisation from Drug Regulatory Authority of Pakistan (DRAP).

This marks both Pakistan's first regulatory approval for a denosumab biosimilar and Mabwell's first overseas marketing authorisation for its products.

9MW0311 is a recombinant fully humanized anti-RANKL monoclonal antibody injection (60mg), developed as a Prolia® biosimilar. On March 28, 2023, the marketing application for 9MW0311 was approved by the National Medical Products Administration (NMPA) for the treatment of postmenopausal women with osteoporosis at high risk of fracture in China.

9MW0321 is a recombinant fully humanized anti-RANKL monoclonal antibody injection (120mg) developed as a XGEVA® biosimilar. The NMPA of China granted marketing approval for 9MW0321 on March 29, 2024, establishing it as China's first approved XGEVA® biosimilar.

As a key Belt and Road Initiative partner with a population of 240 million, Pakistan presents substantial pharmaceutical market potential, aligning with Mabwell's strategic expansion into high-growth emerging markets. Earlier, Mabwell entered into a licensing agreement with Searle to facilitate local fill-finish and commercialisation of Denosumab in Pakistan.