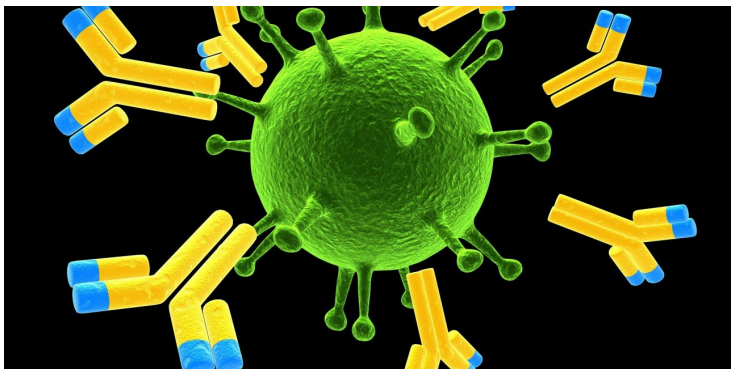
BioSpectrum the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

EVENITYâ??s application accepted by European Medicines Agency

08 January 2018 | News

Application supported by phase 3 data in more than 11,000 postmenopausal Women and Men with Osteoporosis at increased risk of fracture



Amgen and UCB have been working together under a collaboration and license agreement to research, develop and market antibody products targeting the protein sclerostin.

Together, Amgen and UCB announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for EVENITY (romosozumab) for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

If approved in Europe, EVENITY will be a novel osteoporosis treatment that increases bone formation and reduces bone resorption simultaneously to increase bone mineral density (BMD) and reduce the risk of fracture.

The MAA for EVENITY is based on results from three pivotal Phase 3 studies: FRAME, including 7,180 postmenopausal women with osteoporosis; ARCH, including 4,093 postmenopausal women with osteoporosis at high risk for fracture; and BRIDGE, including 245 men with osteoporosis.

The agency will evaluate the clinical benefit: risk profile of EVENITY in these three pivotal studies, including the potential to increase BMD and reduce the risk of fractures in women with osteoporosis, as well as the cardiovascular safety signal seen in the ARCH study.