Biocon Biologics biosimilars for osteoporosis, cancer-related bone disease gets FDA nods

During trials both biosimilars demonstrated comparable quality, safety, and efficacy to the reference product and have been granted provisional interchangeability designation against the reference biologic by the FDA.

New Delhi: Bengaluru-based Biocon fully integrated subsidiary Biocon Biologics announced that the USFDA has approved the company's Denosumab biosimilars: Bosaya and Aukelso indicated for osteoporosis and cancer-related bone.

Bosaya, a biosimilar of blockbuster brand Prolia marketed by Amgen, is a single dose prefilled syringe approved for the treatment of postmenopausal women and men with osteoporosis at high risk for fracture.

The innovative brand is a monoclonal antibody engineered to block RANKL (Receptor Activator of Nuclear Factor Kappa-B Ligand), a protein to reduce bone resorption by regulating the survival of osteoclasts— a cells that break down bone— thereby leading to increased bone density and strength.

As per Amgen financial results, in 2024, Prolia racked up net world wide sales of over $4.3 billion (~ Rs 37,000 crore).

Aukelso is a biosimilar of another Amgen blockbuster brand Xgeva, an IV , marketed for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

During trials both biosimilars demonstrated comparable quality, safety, and efficacy to the reference product and have been granted provisional interchangeability designation against the reference biologic by the FDA, the company said in a release.

In 2024 the innovators brand reported total world wide sales of over $2.2 billion (~Rs 19,000 crore).

Alongside Biocon, Denosumab biosimilars is also marketed by Sandoz, a Novartis subsidiary in the US while in India the therapy has been developed by Mumbai-based Alkem Laboratories subsidiary Enzene Biosciences.

Commenting on the development Shreehas Tambe, CEO and MD, Biocon Biologics, said, “With Bosaya, we are proud to offer a more affordable treatment option for patients with osteoporosis, and with Aukelso, we are further expanding our oncology care portfolio.”

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/fda-approves-biocon-biologics-denosumab-biosimilars-for-osteoporosis-and-cancer-treatment/124027958