

Enzene's anti-osteoporosis product Teriparatide receives DCGI nod

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Pune based Enzene Biosciences Ltd has announced that it has obtained marketing authorisation (MA) from the Drug Controller General of India (DCGI) for teriparatide - bioactive part of human parathyroid hormone (PTH), an anabolic approach to the treatment of osteoporosis, compared to the anti-resorptive therapies such as bisphosphates and SERMs.

According to company sources, the clinical trial conducted for Enzene's teriparatide is one of the most comprehensive trials for teriparatide in India which includes PK (Pharmacokinetics), immunogenicity as well as efficacy arm.

The company sources also revealed that the approved product will be marketed through their holding company Alkem Laboratories Ltd and is also exploring other potential partnering opportunities.

According to Dr Himanshu Gadgil, Whole Time Director, Enzene, "Our teriparatide will be launched in a fully compliant pen device. We are excited to bring to Indian patients the highest quality standard biosimilars underlining our commitment towards quality and innovation."

Commenting on the development, Sandeep Singh, Managing Director, Alkem Laboratories Ltd said, "I am pleased with the launch of teriparatide and look forward to many more launches from Enzene in the near future."

Alkem, through its subsidiary Enzene, has invested in biosimilars and would look to translate its success in small molecules in biosimilars as well.