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ASIA EDITION

Lupin and I'rom partner to make denosumab biosimilar available in Japan

August 25, 2022 | News

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Indian firm Lupin has entered into an exclusive licensing agreement with I'rom Group, a leading pharmaceutical company in Japan. Under the terms of the agreement, I'rom will conduct clinical trials along with Lupin, register, distribute and market biosimilar Denosumab in Japan on an exclusive basis.

Denosumab is indicated for the treatment of postmenopausal women with osteoporosis at high risk of fracture and prevention of skeletal-related events in patients with bone metastases from solid tumors among other indications.

Following the completion of the clinical trial and receipt of marketing authorization from PMDA in Japan, I'rom will exclusively commercialize the product in Japan. As part of the agreement, Lupin will receive multiple milestone payments. Currently, Denosumab is available under two brands, Pralia and Ranmark, with a market size of approximately $500 million in Japan.

"In post-menopausal women, osteoporosis is often caused by estrogen decline and is a common condition associated with advancing age. It can result in severe clinical consequences, such as back pain and bone fractures particularly in the spine and hips," said Dr Cyrus Karkaria, President – Biotechnology, Lupin. "In progressing our development programme for denosumab biosimilar, we hope to provide patients with early and expanded access to advanced biologic medicines, which has the potential to change their course of illness."