Lupin gets FDA nod for ranibizumab biosimilar

The drug is approved in both vials and pre-filled syringe presentations and will be available in 0.3 mg and 0.5 mg doses.

New Delhi: Mumbai-based drugmaker Lupin Limited announced that the US Food and Drug Administration (FDA) has approved its Ranluspec(ranibizumab-hkdz) as an interchangeable biosimilar to Genentech's Lucentis.

The drug is approved in both vial and pre-filled syringe presentations and will be available in 0.3 mg and 0.5 mg doses.

Ranibizumab is an endothelial growth factor (VEGF) inhibitor, a signal protein that contributes to abnormal blood vessel growth and leakage in the eye.

It is indicated for treating patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization.

According to IQVIA estimates, the total addressable market opportunity for Lucentis biosimilars is around $210 million.

Vinita Gupta, CEO, Lupin, said, "as our second US biosimilar ranibizumab adds depth to our biosimilars portfolio, reflecting our progress in complex biologics while expanding patient access to proven vision therapies."

Earlier this year, Lupin secured European approval for the drug and entered into an exclusive licensing agreement with Sandoz, out-licensing commercial rights in several markets, including the European Union (excluding Germany), Switzerland, Norway, Australia, Hong Kong, Vietnam and Malaysia.

In France through a separate agreement, the product will be commercialized by two companies, Sandoz and Biogaran.

Meanwhile, Zydus Lifesciences has also in-licensed an FDA approved ranibizumab interchangeable biosimilar from Swiss drugmaker, Bioeq.

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