

CDSCO approves NovaLead's patented repurposed drug for treating diabetic foot ulcer

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A new indication as well as new formulation to be first launched in India



Pune-based NovaLead Pharma has announced that the drug regulator in India, Central Drugs Standard Control Organisation (CDSCO), has approved their patented Repurposed Drug for treatment of Diabetic Foot Ulcer (DFU) which is a global unmet medical need.

With over 15% -25% of diabetic patients suffering from DFU at least once in their lifetime, DFU is the most prevalent complication caused by chronic diabetes. The approval of NovaLead's patented repurposed drug is significant because DFU is the leading cause for lower limb amputations globally, with about 100,000 annual incidences in India alone.

"Although it is a repurposed drug, we developed it as a new drug with comprehensive preclinical and clinical investigations, keeping patient safety at the forefront. Its approval is based on statistically significant positive results over standard of care treatment in a randomised, double blind Phase 3 clinical trial" said Dr Sudhir Kulkarni, Vice President- Discovery, at NovaLead.

This drug is a novel topical gel formulation of Esmolol hydrochloride, which is already approved in several countries for cardiac conditions via intravenous injection. Thus, this novel topical gel discovered and developed by NovaLead is a new indication as well as new formulation to be first launched in India. NovaLead has been granted patents for this drug in several countries including regulated markets of USA, EU and Japan.

"The drug will be made available to the patients of DFU in India by one of the leading Indian pharmaceutical companies through an exclusive IP licensing arrangement with NovaLead. Going forward, NovaLead will focus on the development of this repurposed drug for regulated markets of USA and Europe" said Supreet Deshpande, Chief Executive Officer at NovaLead Pharma.