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Lakewood-Amedex advances Nu-3 gel toward Phase 2a diabetic foot ulcer trial

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The Bisphosphocin antimicrobial gel showed preclinical safety data supporting clinical dose selection for infected diabetic foot ulcers.

Lakewood-Amedex Biotherapeutics has announced preclinical safety data supporting clinical dose selection for its upcoming Phase 2a trial of Nu-3 Gel in infected diabetic foot ulcers.

Nu-3 is a gel formulation of a Bisphosphocin compound being developed as a topical antimicrobial therapy. The company is positioning the product for infected diabetic foot ulcers, where local infection, resistant bacteria and biofilm formation can complicate wound healing.

This is relevant because diabetic foot ulcers remain a major complication of diabetes and can lead to hospitalisation, amputation and long-term disability. Infected wounds are particularly difficult to manage because patients may have poor circulation, impaired immune response and complex bacterial colonisation.

The preclinical safety study found that Nu-3 was well tolerated at dose levels substantially higher than those selected for the planned Phase 2a trial. Lakewood-Amedex also reported very low systemic exposure, supporting the potential for localised antimicrobial activity with lower risk of systemic side effects.

The company said Nu-3 did not inhibit wound healing in the safety study. This is important because antimicrobial therapies for wounds must control infection without impairing tissue repair.

The upcoming Phase 2a trial will evaluate 2 per cent, 5 per cent and 10 per cent gel concentrations. The selected doses are intended to provide information on both antimicrobial activity and safety in patients with infected diabetic foot ulcers.

Nu-3 is part of Lakewood-Amedex's Bisphosphocin platform, a class of fast-acting broad-spectrum antimicrobials being developed to address infectious diseases and antibiotic-resistant bacterial strains, including MRSA and VRE.