

Lakewood-Amedex Inc. Reports Positive Top-Line Data from Randomized Controlled Phase 1/2a Trial of Nu-3 Antimicrobial in Patients with Infected Diabetic Foot Ulcers

Data to be presented at BioPharm America Conference Today at 10:15 AM ET

SARASOTA, Fla., September 27, 2017 - Lakewood-Amedex Inc., a leading developer of novel anti-infective pharmaceuticals, today announced it will present at the BioPharm America Conference top-line Phase 1/2a clinical data for its lead program, topically applied Nu-3 antimicrobial, to eliminate infection and promote wound healing in patients with infected diabetic foot ulcers (DFU). Nu-3, which belongs to a proprietary class of antimicrobials called Bisphosphocins[®], was well-tolerated in this clinical trial, with no reported adverse events related to treatment. Median wound area reduction (change from baseline) was 65.5% in the 2% Nu-3 treatment arm, versus 29.9% in the placebo arm.

Dr. Alexander Reyzelman, Principal Investigator of the study, Associate Professor in the Department of Medicine at the California School of Podiatric Medicine at Samuel Merritt University, and Co-director of the UCSF Center for Limb Preservation stated, "This new class of antimicrobials is very interesting and has significant implications in our treatment of infected diabetic foot ulcers and wounds. The Phase 1/2a clinical data is very promising and I look forward to seeing the data from the next phase of the clinical trial."

Steve Parkinson, Lakewood-Amedex's CEO and President, said "We are very pleased with the safety and tolerability profile of Nu-3, and while the study was not powered to show efficacy, we are excited by the positive trends that we see. We believe the development of this novel antimicrobial will be critical in the fight against serious antibiotic-resistant bacterial infections, both Gram-positive and Gram-negative. Having demonstrated the safety and tolerability of Nu-3 and based on the encouraging results in the Phase 1/2a trial, we are progressing with our formulation of Nu-3 into a commercially-viable topical hydrogel at concentrations of 2% and greater and will continue into the next phase of DFU clinical studies."

The top-line clinical results will be presented today at BioPharm America™:

Event:	BioPharm America
Date:	Wednesday, September 27, 2017
Time:	10:15 a.m. (Eastern Time)
Location:	Sheraton Boston Hotel

The randomized, multi-center, double-blind, placebo-controlled Phase 1/2a clinical trial was designed as a dose-escalating study to evaluate the safety and tolerability of topically applied Bisphosphocin Nu-3 in patients with Type I or II diabetes mellitus and an infected DFU. The study met its primary endpoints of safety and tolerability, and showed a dose-dependent efficacy trend. Future trials will use hydrogel formulations of Nu-3 at escalating concentrations.

[About Lakewood-Amedex, Inc.](#)



Lakewood-Amedex is a clinical stage pharmaceutical company developing a broad portfolio of anti-infective products, including first-in-class antimicrobial compounds. The Company's products and technology are covered by an extensive patent portfolio consisting of 74 granted and/or issued patents and 13 pending patent applications covering many major pharmaceutical markets. The Company's lead therapeutic candidate is a novel synthetic broad spectrum antimicrobial proven to be effective in killing a wide range of Gram-positive, Gram-negative and antibiotic-resistant bacteria and has recently completed a Phase 1/2a clinical trial in patients with infected diabetic foot ulcers (DFU).

Forward-Looking Statements

This press release contains forward-looking statements that can be identified by terminology such as "expects", "potential", "suggests", "may", "will" or similar expressions. Such forward-looking statements regarding our business, which are not historical facts, are "forward-looking statements" that involve risk and uncertainties, which could cause the Company's actual results and financial condition to differ materially from those anticipated by the forward-looking statements. Actual results may differ materially from statements made as a result of various factors, including, but not limited to sufficiency of cash to fund the Company's planned operations, risk associated with inherent uncertainty of product research and development, risk of protecting proprietary rights and competition. Forward-looking statements speak only as to the date they are made. The Company does not undertake to update forward-looking statements to reflect the circumstances or events that occur after the date the forward-looking statements are made.

Contacts:

[Tiberend Strategic Advisors, Inc.](#)

Jonathon Brzezinski, Ph.D. (investors)

jbrzezinski@tiberend.com

(212) 375-2681

[Tiberend Strategic Advisors, Inc.](#)

David Schemelia (media)

dschemelia@tiberend.com

(212) 375-2686