Data with topical pravibismane for infected chronic diabetic foot ulcers in first-to-podium research at SAWC Spring/WHS

Microbion Phase 2 study shows favorable safety and early efficacy data, with 46.7% of patients treated achieving complete wound closure.

GRAPEVINE, TX, UNITED STATES, May 3, 2025 /EINPresswire.com/ -- A Microbion Corporation exploratory Phase 2a study shows encouraging results on the safety, tolerability, and efficacy of topical pravibismane in adults with moderately infected diabetic foot infections (DFIs).

> “As the first compound in a new drug class, pravibismane provides uniquely broad-spectrum biofilm eradication activity.”
> *Dr. Brett Baker, Founder and Chief Innovation Officer at Microbion*

Key Findings:
- Topical pravibismane (2.5mg/ml) was safe and well-tolerated over 12 weeks of treatment.
- 46.7% of patients treated with pravibismane plus standard of care (SoC) achieved complete wound closure compared with 31.3% in the SoC alone group—a 15.4% (1.5-fold) therapeutic improvement over SoC alone.
- In a subset of study subjects that did not receive systemic antibiotics as part of SoC, 52.6% of patients achieved complete wound closure with pravibismane as the sole pharmacologic intervention compared with 20.0% in the SoC alone group—a 32.6% (2.5-fold) therapeutic improvement over SoC alone.

The randomized, controlled trial was presented as First-To-Podium research at the 2025 Symposium on Advanced Wound Care (SAWC) Spring/Wound Healing Society (WHS) by Dr. Brett Baker, Founder and Chief Innovation Officer at Microbion. Microbion’s findings reinforce the growing interest in topical, biofilm-targeting therapies that offer broad-spectrum efficacy without systemic toxicity—an urgent need in the treatment of chronic diabetic wounds.

This groundbreaking study marks a step forward in the development of enhanced topical treatments for chronic, biofilm-associated wounds. Pravibismane is a first-in-class drug that offers broad-spectrum, anti-infective, anti-biofilm, and anti-inflammatory effects. With a novel mechanism of action, it disrupts microbial bioenergetics, which hinders the ability of microbes to replicate, maintain biofilms, and survive.

“As the first compound in a new drug class, pravibismane provides uniquely broad-spectrum biofilm eradication activity,” Baker said. “Pravibismane also exerts anti-inflammatory effects, which, considering the unresolving nature of inflammation in DFIs and DFUs, may be important in allowing these chronic wounds to heal.”

The study included 47 patients randomized 2:1 to receive either pravibismane plus standard of care (SoC) or SoC alone. SoC included an initial course of systemic antibiotics, sharp debridement, dressing changes and offloading. Pravibismane was applied topically three times per week for up to 12 weeks. At the end of treatment, 46.7% of patients in the pravibismane arm achieved complete wound closure compared to 31.3% in the SoC arm—a 15.4% (1.5-fold) therapeutic improvement favoring pravibismane. Median percent reduction in wound area was also greater in the pravibismane group (-98.5%) compared to SoC (-65.7%).

An unadjusted ad-hoc analysis of 29 subjects who did not receive systemic antibiotics as part of the SoC were also analyzed, providing an opportunity to assess the effect of pravibismane as the sole pharmacologic agent treating moderate DFI. In this population complete wound closure was achieved in 52.6% in the pravibismane group compared to 20% in the SoC group – a 32.6% (2.5-fold) therapeutic improvement favoring pravibismane. While the study was not powered for statistically significant efficacy, investigators observed consistent trends across several efficacy endpoints.

There were no drug-related adverse events due to pravibismane treatment. Pharmacokinetic data also showed no systemic absorption or accumulation of pravibismane or its metabolites. More information about the study can be found on Clinicaltrials.gov (identifier number: NCT05174806).

Unlike systemic antibiotics, which often disrupt the body’s natural microbiome and which can stress organs like the kidneys, pravibismane is administered directly to the wound site.

“Pravibismane does not compromise the normal flora in the rest of the body, nor exacerbate comorbidities that can be associated with systemic antibiotic use,” Dr. Baker said. “We believe that the multi-modal activity provided by topical pravibismane in a single, convenient-to-use agent that could reduce the use of systemic antibiotics while offering improved safety and treatment convenience; healthcare providers and patients do not need to switch therapeutic modalities or combine them.”

Looking ahead, Microbion plans to evaluate pravibismane’s role in reducing major complications of DFIs, such as limb loss.

“Preventing infection-related limb loss remains an unmet need in the field of advanced wound care,” Dr. Baker emphasized. “It is our hope, in registrational Phase 3 clinical studies, to demonstrate reduced rates of infection-related amputation with pravibismane, addressing this

critically important unmet need."

About diabetic foot ulcers:

Approximately one third of people with diabetes develop a foot ulcer during their lifetime. Annually 18.6 million people worldwide and 1.6 million in the US are affected, and about half of the ulcers become infected.1 Updated evidence-based guidelines emphasize the importance antimicrobials for prompt treatment to avoid more serious complications such as osteomyelitis and amputations.2

References:
1. Voelker R. What Are Diabetic Foot Ulcers? JAMA. 2023;330(23):2314. doi:10.1001/jama.2023.17291
2. Senneville et al. IWGDF/IDSA Guidelines on the diagnosis and treatment of diabetes-related foot infections (IWGDF/IDSA 2023). Diabetes Metab Res Rev. 2024 Mar;40(3): e3687. doi: 10.1002/dmrr.3687

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