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Vendor ViewPoint

# BIOMENDICS BRINGS NEW HOPE FOR EPIDERMOLYSIS BULLOSA SIMPLEX PATIENTS AS TAMES-02 TRIAL ADVANCES AND JPM WEEK APPROACHES

By **Karen McGuire,** PhD, CEO and Founder, BioMendics, LLC

As BioMendics prepares to share its progress during the 2026 J.P. Morgan Healthcare Conference and Biotech Showcase, the Ohio-based biotech is advancing what could become the first disease-modifying therapy for Epidermolysis Bullosa Simplex (EB Simplex).

For families living with EB Simplex, each day can mean fragile blistering skin with constant and intense pain that impacts mobility and daily activities. . The condition, caused by gene mutations that weaken the skin's structural proteins, leaves even the lightest friction capable of causing blistering. Despite decades of research, there are still no FDA-approved treatments - only palliative wound care and infection management.

This unmet need is what drives BioMendics, LLC, a Cleveland-based biotech, to pursue a first-in-class topical therapy called TolaSure™, designed to strengthen keratinocyte integrity and directly reduce blister formation at the molecular level. As the company prepares for Biotech Showcase 2026 in San Francisco this January, it is also marking a key milestone: the active enrollment of its clinical study, TAMES-02, for patients with moderate to severe forms of EB Simplex.


Karen McGuire

"Our mission at BioMendics is to bring science and compassion together for families who have waited far too long for effective treatment," said Dr. Karen McGuire, Founder and CEO of BioMendics. "TolaSure represents an entirely new approach to EB Simplex therapy — one that targets the biology of the disease instead of just managing symptoms."

## TAMES-02: A Collaborative Pathway to Progress

Launched in August 2025, TAMES-02 is a multicenter, randomized, double-blind, placebo-controlled clinical trial co-led by two of the most respected research teams in dermatology: the Northwestern Feinberg School of Medicine Department of Dermatology and the Stanford University School of Medicine Department of Dermatology.

The trial is evaluating TolaSure, a topical treatment for generalized intermediate to severe EB Simplex patients aged four years and older, over the course of 6 months:

- A two-month randomized phase, where participants receive either TolaSure or placebo gels;
- A two-month extension, where all participants receive TolaSure; and
- A follow-up after a two-month period to assess sustained outcomes.

A major focus of the trial is on blister surface area changes over treated body regions. EB Simplex is a dynamic blistering disease which can be better examined when a large body surface area is treated. Plantar blistering (the soles of the feet), one of the most painful and functionally limiting aspects of EB Simplex, is also being assessed for patients that opt to treat their feet. The goal of this trial is to gain a deeper understanding of meaningful outcomes for the EB Simplex community, an important step in the approval of a new therapy.

**Our progress this year marks an inflection point for BioMendics and for families living with EB Simplex worldwide.**

Dr. Joyce Teng, Principal Investigator at Stanford University, shared:

"Our early studies with TolaSure showed meaningful reduction in blistering, which is incredibly encouraging for the EB Simplex community. Clinical research in rare skin diseases requires collaboration with companies like BioMendics and patient advocacy groups like debra of America to accelerate progress toward transformative therapies. Our shared goal is to bring hope and healing to families who have had so few options for so long."

Dr. Amy Paller, Principal Investigator at Northwestern University, added:

"TAMES-02 is a vital next step. The collaboration with BioMendics and Stanford enables us to rigorously evaluate this therapy and, hopefully, bring real progress to patients who have had limited options for far too long."

## Moving Beyond Bandages

EBS accounts for roughly 70% of the 80,000 epidermolysis bullosa cases in the U.S., translating to an effective addressable market of 35,000 patients. According to patient surveys, 92% of those affected cite blistering and skin fragility as their top concern — a reminder that symptom management remains inadequate.

BioMendics' therapy, TolaSure, has already received U.S. FDA Orphan Drug Designation and Rare Pediatric Disease Voucher eligibility, paving the way for accelerated approval opportunities. The company's patent portfolio now spans 12 issued patents across major global markets and 15 pending, supporting both regulatory progress and commercial scalability.

## Looking Forward to 2026

As BioMendics heads into Biotech Showcase 2026 during JPM Week, the timing couldn't be more strategic. The company's ongoing TAMES-02 trial positions it as a lead disease-modifying developer in active mid-stage clinical testing for an EB Simplex therapy. Combined with strong intellectual property, regulatory milestones, and high-profile academic collaborators, BioMendics has captured the attention of investors focused on innovation in rare dermatology.

"TolaSure's potential impact extends beyond treating blisters — it's about restoring confidence, mobility, and comfort for people who've endured daily pain," McGuire said LS

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