



# BIO MendICS

4209 State Route 44  
Rootstown, OH 44272  
[www.biomendics.com](http://www.biomendics.com)

FOR IMMEDIATE RELEASE

## BioMendics Launches TAMES-02 Clinical Trial for Innovative Epidermolysis Bullosa Simplex Therapy

**BioMendics Launches Pivotal TAMES-02 Clinical Trial to Advance TolaSure™ for EB Simplex Patients**

**Rootstown, OH – July 22, 2025** – BioMendics, a clinical-stage biopharmaceutical company focused on rare skin diseases, today announced the launch of the TAMES-02 clinical trial—a multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of *TolaSure™*, a first-in-class topical therapy for patients with generalized intermediate to severe *Epidermolysis Bullosa Simplex* (EB Simplex).

EB Simplex is a rare, inherited skin disorder that causes painful blistering due to fragile skin, affecting an estimated 35,000 individuals worldwide. With current treatment limited to wound care and infection control, patients and families face a lifelong battle without disease-modifying options. *TolaSure*, developed by BioMendics, aims to change that reality by targeting the mutant keratins that underlie skin fragility, offering a novel mechanism to reduce blister burden and improve quality of life.

The TAMES-02 trial builds on the success of the earlier TAMES-01 study, which demonstrated *TolaSure's* safety and efficacy in adult patients.

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.”*



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TAMES-02 is being conducted in partnership with Stanford University School of Medicine and Northwestern University Feinberg School of Medicine—two globally recognized leaders in dermatology research. The trial will evaluate *TolaSure* in patients aged 4 and older and includes a 2-month double-blind, placebo-controlled phase, followed by a 2-month open-label phase where all participants receive *TolaSure*, and a 6-month follow-up. Importantly, the trial allows patients to treat plantar (foot) blistering—a major source of pain and disability for those living with EB Simplex.

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.”*

“We’re really excited to be able to cover travel cost to bring patients in from all over the United States and internationally.” said Dr. Aleesha McCormick Senior clinical research scientist at BioMendics. “EB Simplex patients don’t all live close to an Academic Medical Center like Stanford and Northwestern and our goal is to help as many patients be able to participate in the study as possible. Our study design also lets us recruit slightly less severe patients that may not have flared enough to be eligible for other clinical studies.”

“Our mission is to bring meaningful therapies to patients living with rare diseases like EB Simplex—conditions that have been overlooked for too long,” said Dr. Karen M. McGuire, CEO and Founder of BioMendics. “With *TolaSure*, we’re targeting the root cause of blistering by reinforcing fragile keratinocytes. The TAMES-02 trial is a critical step toward proving safety and efficacy. If successful, we’ll seek strategic partnerships to help accelerate development and deliver this treatment to patients as quickly as possible. We also see strong potential for *TolaSure* in other rare keratin disorders such as pachyonychia congenita and epidermolytic ichthyosis.”

TAMES-02 reflects BioMendics’ ongoing commitment to developing innovative, targeted treatments for rare skin disorders and is currently open for patient enrollment.

**To learn more or inquire about participation, visit [www.biomendics.com](http://www.biomendics.com) or contact the study sites below:**



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## **Stanford University Dermatology**

*Dr. Joyce Teng* (Principal Investigator)

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Questions about participant rights: 1-866-680-2906

## **Northwestern University Dermatology**

*Dr. Amy Paller* (Principal Investigator)

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***Questions about participant rights: 312-503-7110***

### **About BioMendics:**

For more information about BioMendics please visit our website ([www.biomendics.com](http://www.biomendics.com)).

BioMendics is proud to be a REDlzone company at Northeast Ohio Medical University (NEOMED). The REDlzone (Research, Entrepreneurship, Discovery, and Innovation Zone) supports local life science and biomedical entrepreneurs by providing access to NEOMED's resources, expertise, and connections to the region's innovation ecosystem. This partnership has been instrumental in advancing TolaSure from research to clinical development.

### **Contact:**

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