Hudson Therapeutics, the U.S. Subsidiary of Shaperon, Announces Initiation of Phase 2b Part 2 Clinical Trial for Nugel

Next-Generation Atopic Dermatitis Treatment Moves Forward with Global Development and Licensing Opportunities

Hudson Therapeutics, Inc.

DURHAM, NC, UNITED STATES, March 5, 2025 /EINPresswire.com/ -- Hudson Therapeutics, the U.S. subsidiary of Shaperon, announced today that Shaperon will commence the Phase 2b Part 2 of its clinical trial for Nugel, a first-in-class inflammasome inhibitor designed to treat mild to moderate atopic dermatitis. A kickoff meeting was recently held in March in the United States, marking a significant milestone in the global clinical development of Nugel. The clinical trial will be conducted across 12 U.S. and South Korean clinical sites, enrolling 177 patients of diverse ethnic backgrounds. This study plans to evaluate the safety and efficacy of Nugel further following the successful completion of Phase 2b Part 1. Patient enrollment begins in March 2025, with dosing expected to conclude by December 2025. Final clinical data will be available in the first half of 2026. Nugel, a topically administered drug, utilizes inflammasome inhibition, a novel mechanism designed to reduce inflammation and potentially improve long-term safety for patients with atopic dermatitis.

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> *Janice Marie McCourt, CEO of Hudson Therapeutics*

In Phase 2b Part 1, Nugel demonstrated an excellent safety profile and better efficacy compared to currently marketed treatments, with key findings including:

- Eczema Area and Severity Index (EASI) – Nugel showed better score improvement versus competitive treatments.
- EASI-50 Response Rate – 100% of patients in a specific Nugel dosage group achieved the EASI-50 criteria, representing a 56% improvement over the trial's placebo arm.
- IGA Treatment Success (IGA-TS) – Nugel achieved a 39% higher clinical remission rate versus

the placebo, a key FDA approval benchmark.

"We are excited to initiate Phase 2b Part 2 of Nugel's clinical trial, building on the promising results from the previous phase," said Seung-Yong Seong, CEO of Shaperon. "This study will further validate Nugel's efficacy and long-term safety, reinforcing its potential as a transformative treatment for atopic dermatitis. We are confident that this large-scale global trial will generate valuable clinical trial data, bringing us one step closer to delivering an innovative therapy to patients worldwide."

Shaperon, Inc.

To prepare for this next trial phase, Shaperon has partnered with leading U.S. clinical research institutions, including Cahaba Dermatology Skin Health Center and L.A. Universal Research Center, as well as eight additional clinical trial sites across the U.S. The trial will also be conducted in South Korea, with research sites at Seoul National University Hospital, Bundang Seoul National University Hospital, Severance Hospital, and Sejong Chungnam National University Hospital.

With highly promising safety and efficacy results, Hudson Therapeutics, as the U.S. subsidiary of Shaperon, is actively pursuing global pharmaceutical partnerships for potential licensing and commercialization of Nugel.

"Hudson Therapeutics is committed to advancing innovative therapies, and we recognize Nugel's global potential in the mild to moderate atopic dermatitis market," said Janice Marie McCourt, CEO of Hudson Therapeutics. "We have strong interest from numerous specialty pharmaceutical companies and we are actively engaged in contracting a top tier partner to commercialize NuGel. The growing demand for thirty-five million patients globally with atopic dermatitis presents a significant market opportunity, and we believe Nugel has the potential to redefine the standard of care. Through global partnerships, we aim to accelerate its path to commercialization and bring this breakthrough therapy to patients worldwide."

ABOUT SHAPERON

Shaperon is a clinical-stage biotech company focused on developing novel inflammasome inhibitors. Its unique GPCR19-P2X7 modulation mechanism suppresses a range of inflammatory cytokines, including IL-1β, IL-18, IL-6, and TNF-α, by targeting both priming and activation phases of the inflammasome. This pioneering approach addresses complex immune-mediated inflammatory disorders, with Shaperon currently advancing clinical programs in Atopic Dermatitis, Alopecia Areata, Alzheimer's disease, and COVID-19 pneumonia, in addition to preclinical programs in MASH and obesity.

ABOUT Hudson Therapeutics
Hudson Therapeutics, a US subsidiary of Shaperon, was established and incorporated in the US in 2023 to lead global clinical trials, commercial strategy, M&A, business development, and investor relations of Shaperon's assets. Hudson also plans to develop Shaperon's early-stage preclinical assets in the future.

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