Hudson Therapeutics Announces Completion of Phase 2b Part 1 Clinical Trial for Nugel

SAN FRANCISCO, CA, UNITED STATES, January 16, 2025 /EINPresswire.com/ -- Hudson Therapeutics, the U.S. subsidiary of Shaperon, announced the successful completion of Part 1 of the U.S. Phase 2b clinical trial for Nugel, the world's first inflammatory complex inhibitor treatment for atopic dermatitis.

Hudson Therapeutics, Inc.

Shaperon, Inc.

Following an independent review, the Safety Monitoring Committee (SMC) has recommended advancing to Part 2 of the trial, a critical step toward full-scale efficacy evaluation. Conducted under FDA guidance, Part 1 was designed to assess preliminary safety in a multi-ethnic U.S. cohort before efficacy testing.
To ensure robust safety data, the trial increased Nugel dosages up to eightfold compared to prior trials conducted in South Korea. It extended the study period to eight weeks, doubling the duration of earlier studies.

The safety evaluation, which tested four different Nugel doses and a placebo, revealed no significant side effects linked to the drug. Adverse events were minimal and comparable to the placebo group, with 0-1 drug-related cases per treatment group versus 2 in the placebo group. Even at higher doses and extended durations, Nugel demonstrated exceptional tolerability.

Nugel achieved the EASI 50 index in efficacy assessments, a benchmark for atopic dermatitis treatments. At an optimized dose, 100% of patients reached EASI 50, compared to 44% in the placebo group. Furthermore, Nugel demonstrated comparable or superior performance against FDA-approved competitor drugs for mild to moderate atopic dermatitis.

The drug also achieved significant results in IGA-TS metrics, with a clinical response rate surpassing 39% in a specific dose group—matching or exceeding top-performing competitor treatments.

“Completing Phase 2b Part 1 with such promising safety and efficacy data strengthens our confidence in Nugel’s transformative potential. We are excited to proceed to the next clinical development phase and continue our work to bring this groundbreaking treatment to patients globally,” said Janice Marie McCourt, CEO of Hudson Therapeutics. “Leveraging these promising results, Hudson Therapeutics is actively engaging global pharmaceutical companies in out-licensing discussions at leading industry events, including numerous meetings around the 43rd Annual Healthcare JP Morgan Healthcare Conference.”
Dr. Seung-Yong Seong, CEO of Shaperon, added, “Nugel’s ability to deliver exceptional efficacy while maintaining an outstanding safety profile represents a major advancement in the treatment of atopic dermatitis. These results validate our unique inflammasome inhibition platform, and we are eager to collaborate with global partners to ensure its success in markets worldwide.”

With Part 1 successfully completed, Part 2 will involve a larger, diverse cohort of 177 patients across 12 U.S. clinical sites, with four additional sites planned in both the U.S. and South Korea. The expanded trial reinforces Nugel’s efficacy and safety profile while advancing toward regulatory approval in the US and South Korea.

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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