Hudson Therapeutics and Shaperon Report Positive Result of Phase 2B Part 1 for Nugel at JPM 2025

DURHAM, NC, UNITED STATES, January 24, 2025 /EINPresswire.com/ -- Hudson Therapeutics and Shaperon announced on January 24th that they engaged in in-depth discussions about out-licensing their next-generation atopic dermatitis treatment, NuGel, with global pharmaceutical companies at the JP Morgan Healthcare Conference in the United States. These discussions were based on the U.S. Phase 2b (Part 1) clinical trial results.

Hudson Therapeutics and Shaperon have shared various data on NuGel under confidentiality agreements with multiple global companies. At the JPM Conference, follow-up meetings were held with companies that had already signed confidentiality agreements and formal licensing discussions were initiated with eleven global pharmaceutical companies, including top multinational leaders in dermatology. Hudson Therapeutics and Shaperon plan to continue these negotiations in the coming months.

NuGel is the world's first atopic dermatitis treatment developed with a novel inflammasome inhibition mechanism. On January 10, Part 1 of the U.S. Phase 2b trial passed an independent review by the Safety Monitoring Committee (SMC) following FDA guidelines. Clinical trial results showed that drug-related adverse events occurred in 0–1 subjects per treatment group and two subjects in the placebo group, confirming safety. No severe drug-related adverse events were observed.

Regarding clinical efficacy, NuGel demonstrated outstanding results: 100% of patients in a specific dosage group achieved EASI-50, with a 56% higher response rate than placebo. This exceeded the placebo-adjusted response rates (15–40%) of FDA-approved competing treatments. Additionally, for the key efficacy metric IGA-TS, NuGel achieved over a 39% remission rate compared to placebo, highlighting efficacy equal to or better than competing therapies.

Based on these promising safety and efficacy outcomes from Part 1, Hudson Therapeutics and Shaperon plan to expand the trial in Part 2 to include 177 patients in the U.S. and Korea. Patients will be treated with two dosages of NuGel (1% and 2%) over an eight-week period, aiming to secure significant efficacy and safety data. Given the positive results from Part 1, the company anticipates similarly superior outcomes in Part 2 compared to competing treatments.

Janice Marie McCourt, CEO of Hudson Therapeutics, commented, “The companies we met at JPM

were highly interested in the Part 1 results of NuGel. The clinical trial demonstrated positive safety and efficacy data across diverse ethnic groups in the U.S., attracting significant attention from global pharmaceutical companies. NuGel offers superior efficacy and drastically reduced side effects compared to currently marketed treatments, positioning it for competitive advantages."

Dr. Seung-Yong Seong, Founder and CEO of Shaperon, stated, "We plan to swiftly initiate Part 2 of the Phase 2b trial by February while accelerating licensing negotiations with global pharmaceutical companies. We will also leverage the success of NuGel's licensing to expedite R&D for our other major pipeline programs."

Earlier, Shaperon also participated in the BFC Global Healthcare Conference held in San Francisco, where it presented NuGel and its core pipeline during a company roadshow. During this event, forty global and regional companies expressed interest in the Phase 2b Part 1 results and requested follow-up meetings, where further licensing negotiations will be conducted.

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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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