

# Escient Pharmaceuticals Initiates Clinical Proof-of-Concept Study of EP262, a First-in-Class Oral MRGPRX2 Antagonist, in Chronic Spontaneous Urticaria

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- Efficacy and safety of EP262 to be assessed in a randomized, placebo-controlled study in ~90 patients
- Second of three clinical proof-of-concept studies to be initiated in second half of 2023

SAN DIEGO--(BUSINESS WIRE)-- Escient Pharmaceuticals, a clinical-stage drug development company advancing novel small molecule therapeutics for systemic neuro-immune disorders, today announced that the first subject has been dosed in CALM-CSU, a Phase 2 clinical proof-of-concept study of EP262 in subjects with chronic spontaneous urticaria (CSU).

By blocking activation of MRGPRX2 and degranulation of mast cells, EP262 has the potential to effectively treat multiple mast cell mediated diseases with an initial focus on chronic urticaria (hives) and atopic dermatitis (eczema). EP262 represents a novel, targeted approach to the treatment of these disorders with the potential for once-daily oral administration without the side effects observed with other approaches.

"Chronic spontaneous urticaria is a debilitating condition driven by activation of mast cells, and there is growing evidence that non-IgE mediated mast cell activation via MRGPRX2 may play an important role in the disease," said Christian Weyer, M.D., M.A.S, Chief Medical Officer at Escient. "We are excited to initiate Phase 2 clinical development of EP262 for CSU, as it has the potential to become a much needed, once daily oral treatment option that is safe and able to alleviate the spontaneous occurrence of itchy hives via a novel, highly targeted mechanism."

CALM-CSU is a randomized, double-blind, placebo-controlled Phase 2 study designed to evaluate the efficacy, safety

and tolerability, and pharmacokinetics of EP262 in approximately 90 patients with CSU who are inadequately controlled with H1-antihistamines. Patients will be randomized, in a 1:1:1 ratio, to treatment with EP262 50 mg, EP262 150 mg, or placebo, administered orally, once daily for 6 weeks, followed by an off-treatment follow-up period. The primary efficacy endpoint is the change from baseline in the urticaria activity score over 7 days (UAS7), a validated and widely used measure of disease activity. More information about this study is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT6077773).

## About EP262

EP262 is a potent, highly selective once-daily small molecule antagonist of MRGPRX2, a receptor expressed on mast cells that is activated by numerous ligands, including many peptides released from sensory neurons as well as other cell types. In response to MRGPRX2 activation, mast cells release histamine, tryptase, chymase, chemokines and cytokines, which can cause itchy hives, angioedema, type 2 inflammation (through engagement of the adaptive immune system) and chronic pruritus and pain. Escient's preclinical data demonstrates that, by blocking activation of MRGPRX2, EP262 has the potential to effectively treat a broad range of mast cell-mediated diseases, with an initial focus on chronic urticarias and atopic dermatitis.

## About Chronic Urticaria

Chronic urticaria, defined as urticaria persisting for more than 6 weeks, manifests with very itchy hives that may vary in size and can significantly impact a patient's quality of life by interfering with sleep and daily activities. Some patients with chronic urticaria may also develop swelling deeper under the skin or in other tissues (angioedema). There are two main forms of chronic urticaria. In chronic spontaneous urticaria (CSU), hives occur spontaneously, without known triggers. In chronic inducible urticaria (CIndU), hives are induced by specific triggers such as cold exposure (cold urticaria) or touch (symptomatic dermographism), among others.

## About Escient Pharmaceuticals

Escient Pharmaceuticals is a clinical-stage company focused on developing novel therapeutics to address a broad range of neurosensory-inflammatory disorders. The company's pipeline includes two first-in-class small molecule antagonists targeting MRGPRX2 for the treatment of various mast cell mediated disorders and MRGPRX4 for cholestatic pruritus. Based in San Diego, California, Escient is led by an experienced management and scientific team and funded by top-tier life science investors.

Visit [www.escientpharma.com](http://www.escientpharma.com) to learn more.

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