

Evommune Announces Positive Proof-of-Concept Clinical Trial Results for its MRGPRX2 Antagonist (EVO756)

- EVO756 demonstrated an excellent safety profile and was well tolerated at all doses; pharmacokinetic data supports once-daily oral dosing
- EVO756 is a potent and highly selective small molecule antagonist of MRGPRX2
- Evommune to initiate multiple Phase 2 trials

Palo Alto, Calif., July 16, 2024 – Evommune, Inc., a clinical stage biotechnology company discovering and developing new ways to treat immune-mediated inflammatory diseases, today announced positive results of its first-in-human proof-of-concept study with EVO756. By blocking MRGPRX2 activation and degranulation of mast cells, EVO756 has the potential to be a first-in-class oral treatment for a variety of mast cell-mediated diseases. Evommune is planning to present a comprehensive data set of this trial at a peer-review scientific meeting in the fall of 2024.

"The data from our proof-of-concept trial exceeded our expectations, and we now plan to initiate multiple clinical trials of EVO756, including a Phase 2b study in chronic spontaneous urticaria (CSU) patients during the first half of 2025," said Eugene Bauer, M.D., Chief Medical Officer at Evommune. "We believe we have a novel, highly potent and selective agent that can be orally administered once daily, with broad opportunity for patients suffering from various mast-cell mediated diseases."

The proof-of-concept study is a randomized, double-blind, placebo-controlled single and multiple ascending dose (SAD and MAD) study in normal healthy adults and assessed the safety, tolerability, pharmacokinetics and pharmacodynamics/target engagement of orally administered EVO756. Doses from 1 mg to 500 mg were administered in ascending order across 7 cohorts of 8 subjects each (6 active, 2 placebo). In the MAD cohorts completed to date, ascending doses of 10 mg, 30 mg, 100 mg and 240 mg BID have been administered across 4 cohorts of 16 subjects each (12 active and 4 placebo).

The pharmacodynamic potential of EVO756 on mast cell degranulation was assessed in a skin challenge test, in which icatibant, a known ligand of the MRGPRX2 receptor, was administered intradermally, resulting in measurable skin responses in all MAD participants. Multiple experimental methods have determined that mast cell degranulation caused by icatibant is representative to changes associated with MRGPRX2 disease-relevant endogenous ligands. This portion of the study allowed for an evaluation of target engagement and activity in a highly controlled setting and had the benefit of mimicking the potential impact of EVO756 versus placebo in inducible urticarias.

"EVO756's excellent safety profile and potential for a once daily oral dosing provide continued excitement around this new class of therapies in inflammatory diseases. As expected, these data further support the hypothesis that blockade of the MRGPRX2 receptor and its subsequent downstream effect has the potential to treat the root cause of inflammation, offering greater relief than currently available treatments," commented Sarbjit Saini, M.D., Professor of Medicine at Johns Hopkins University in Baltimore, Maryland.

About EVO756

EVO756 is a potent, highly selective small molecule antagonist of mas-related G-protein coupled receptor X2 (MRGPRX2). MRGPRX2 is most abundantly found on mast cells and peripheral sensory neurons. MRGPRX2 can trigger IgE-independent activation (degranulation) via multiple ligands, which can lead to a variety of symptoms depending on the tissue that is affected. Evommune's pre-clinical data demonstrates that by blocking activation of MRGPRX2 and degranulation of mast cells, EVO756 has the potential to be a first-in-class oral treatment for a variety of mast cell mediated diseases. In addition, due to its unique function on peripheral sensory neurons, EVO756 could provide fast relief of itch associated with inflammatory diseases, such as atopic dermatitis.

About Evommune, Inc.

Evommune, Inc., a Palo Alto based biotech company, is creating game-changing science to treat immune-mediated inflammatory diseases by discovering, developing, and delivering therapies that address symptoms and halt progressive disease. For more information, please visit Evommune.com.

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