Kinaset Therapeutics Announces FDA Clearance of IND Application for frevecitinib (KN-002) in Asthma Treatment

Phase 2b study to evaluate novel inhaled therapeutic in patients with inadequately controlled asthma despite medium-to-high dose ICS/LABA therapy

BOSTON, MA, January 29, 2025 — Kinaset Therapeutics, a clinical-stage biopharmaceutical company developing inhaled therapeutics to treat serious respiratory diseases, today announced that the United States Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for frevecitinib (KN-002). This novel inhaled dry powder therapeutic is in development for patients with asthma that remains inadequately controlled by standard of care inhaled maintenance therapies. These patients are typically prescribed medium-to-high dose inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA), with or without additional controllers such as long-acting muscarinic antagonists (LAMA). Kinaset plans to begin a Phase 2b dose ranging trial in mid-2025.

Asthma, one of the most prevalent chronic respiratory conditions worldwide, affects millions of individuals, with nearly 50% of patients experiencing persistent symptoms despite standard treatment. Frevecitinib, a first-in-class inhaled pan JAK inhibitor targeting JAK1, JAK2, JAK3 and TYK2, is specifically formulated to deliver therapeutic lung concentrations through a single-capsule dry powder inhaler, while minimizing systemic exposure.

"The unique mechanism of our inhaled pan-JAK inhibitor, combined with its targeted lung delivery and minimal systemic exposure, positions frevecitinib as a potentially transformative therapy for the treatment of severe asthma," said Christopher O'Brien, MD, PhD, Chief Medical Officer of Kinaset Therapeutics. "Following positive Phase 1 results, we will continue development of a treatment that could significantly improve outcomes for patients whose severe asthma is inadequately controlled with ICS/LABA-based maintenance regimens. We're excited to build on these promising results as we advance into our Phase 2b program."

In Phase 1b studies, frevecitinib demonstrated clinically relevant reductions in fractional exhaled nitric oxide (FeNO)—a key marker of airway inflammation—in patients with both mild asthma and moderate-to-severe asthma. These results included patients with blood eosinophil counts below 300 cells/ mm^3, as well as patients below 150 cells/mm^3, populations often less responsive to other therapies. The Phase 1b study also showed dose-proportional pharmacokinetics with plasma levels below pharmacologically active concentrations, aligning with the absence of systemic or local safety concerns. The upcoming Phase 2b dose ranging study is designed to select the optimal dose regimen for pivotal clinical development.

About Kinaset Therapeutics, Inc.
Kinaset Therapeutics is focused on developing inhaled therapeutics to address significant unmet medical needs in respiratory diseases. With founding investors 5AM Ventures, Atlas Venture and Gimv, the Company is pursuing a patient-focused approach to build a leading respiratory therapeutics company. See more information at the Company's website.

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