Kinaset Therapeutics Announces Dosing Underway in its Phase 1b Study of KN-002 in Healthy Volunteers and Asthma Patients

Two-part Phase 1b trial will evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profile of inhaled pan-JAK inhibitor KN-002

Study is being conducted at the Medicines Evaluation Unit in Manchester, UK

Topline results anticipated in early 2022

BOSTON, MA September 15, 2021 – Kinaset Therapeutics, a biopharmaceutical company developing a next generation anti-inflammatory therapy to treat patients with severe asthma, today announced that the first 24 participants have been dosed in its Phase 1b placebo-controlled study. This trial will evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of KN-002, a novel and potent inhibitor of all Janus kinase (JAK) isoforms (i.e. JAK1, JAK2, JAK3, TYK2) that is formulated as a dry powder for inhaled delivery to the lung.

"This Phase 1b clinical study is an important step in our goal to develop a new therapy to treat patients with severe asthma regardless of the underlying cause of inflammation," stated Robert Clarke, Ph.D., Chief Executive Officer of Kinaset Therapeutics. "KN-002 is designed as a non-invasive alternative to approved parenteral biological drugs, with inhaled administration enabling delivery of therapeutic drug levels directly to the lung while minimizing systemic exposure."

"Severe asthma affects about 10% of the entire asthma population, impacts quality of life and results in recurrent exacerbations that can lead to hospitalization. Unlike existing therapies, KN-002 represents an opportunity to treat all patients with severe asthma and address a significant unmet treatment need particularly for those whose disease is mediated by non-eosinophilic inflammation," said Frazer Morgan, Chief Development Officer at Kinaset Therapeutics. "Successful completion of this Phase 1b study will enable further investigations in patients with stable moderate to severe asthma and chronic obstructive pulmonary disease (COPD) with outcomes facilitating dose selection for subsequent Phase 2 clinical evaluation."

Trial Design and Execution (ClinicalTrials.gov Identifier: NCT05006521)
The KN-002 Phase 1b trial is being conducted in the United Kingdom at the Medicines Evaluation Unit (MEU) under the guidance of Professor David Singh. The study comprises two separate parts; Part 1 will evaluate the safety, tolerability and PK of single ascending doses in up to 48 healthy volunteers; Part 2 involves the safety, tolerability, PK and PD assessment of multiple ascending doses in up to 32 patients with stable asthma who are naïve to inhaled corticosteroid therapy. Changes in fractional exhaled nitric oxide (FeNO) levels, from baseline to the end of treatment, will be the key Part 2 PD endpoint. A more detailed study design overview can be viewed **here**.

About Severe Asthma
Asthma is a complex and heterogeneous disease affecting over 300 million people worldwide, with approximately 10% of patients having severe asthma[1,2]. This population suffers from compromised lung function, frequent exacerbations, reduced quality of life and is associated with a disproportionate number of asthma-related hospitalizations that account for approximately 50% of asthma-related costs[1-4]. Multiple inflammatory pathways are implicated in the pathogenesis of asthma[5-7]; patients with eosinophilic mediated disease, typically characterized by elevated levels of blood eosinophils[7], have benefited from the introduction of parenteral biological therapies whereas those with a non-eosinophilic form continue to suffer from limited availability of safe and effective therapies.

About KN-002
KN-002 is a potent and balanced inhibitor of all JAK isoforms (i.e., JAK1, JAK2, JAK3 and TYK2)[8] under development as a non-invasive anti-inflammatory treatment for all patients with severe asthma plus other irespiratory conditions such as COPD. KN-002 is formulated as a dry powder that has demonstrated excellent delivery efficiency and chemical/physical stability. Topical delivery via inhalation is designed to achieve therapeutic drug concentrations at the site of inflammation in the lung while minimizing systemic exposure levels. KN-002 was licensed from Vectura Ltd. in 2020.

About Kinaset Therapeutics, Inc.
Kinaset Therapeutics is focused on developing inhaled therapeutics to address significant unmet medical needs in respiratory diseases. The Company's lead clinical candidate, KN-002, is a novel and non-invasive anti-inflammatory to treat all patients with severe asthma. With founding investors 5AM Ventures, Atlas Venture and Gimv, the Company is pursuing a patient-focused approach to build a leading respiratory therapeutics company. www.kinasettherapeutics.com.

Company Contact
Roger Heerman – Chief Business Officer
info@kinasettx.com
+1 508-858-5810

Media Contact
MacDougall
Lauren Arnold
larnold@macbiocom.com
781-235-3060

References
1. Kupczyk M, Wenzel S. J Intern Med 2012;272:121–32.
2. Wenzel S. Am J Respir Crit Care Med. 2005; 172; 149–60.
3. Chung KF, Wenzel SE, Brozek JL, et al. Eur Respir J 2014; 43: 343–73.
4. Price D, Fletcher M, van der Molen T. NPJ Prim Care Respir Med 2014; 12; 24: 14009.
5. Godar M, Blanchetot C, de Haard H, et al. MAbs. 2018; 10 (1): 34–45.

6. Peters MC, Mekonnen ZK, Yuan S, et al. J Allergy Clin Immunol. 2014; 133: 388–94.
7. Fahy JV. Nat Rev Immunol. 2015; 15: 57-65.
8. Wiegman C et al., In-vitro evaluation of a new potent, selective pan Janus kinase (JAK) inhibitor VR588. ERJ 2015; 46: PA2130.