INS1009-211 (NCT05176951):

A Study to Evaluate the Safety and Tolerability of Treprostinil Palmitil Inhalation Powder in Participants With Pulmonary Hypertension Associated With Interstitial Lung Disease.

The primary objective of this study is to evaluate the safety and tolerability of treprostinil palmitil inhalation powder (TPIP) compared with placebo

Participants will be administered Treprostinil Palmitil (TPIP) once per day at a starting dose of 80 micrograms (µg). Participants will be titrated up to the highest tolerated dose for each individual participant of between 80 µg and 640 µg during the initial 3 weeks of treatment. The overall treatment period will be 16 weeks.

Eligibility Criteria:

1. Inclusion Criteria:
    a. Males and females must be ≥ 18 to ≤ 75 years of age at the time of signing the informed consent form (ICF).
    b. Diagnosis of pulmonary hypertension (PH) associated with interstitial lung disease (ILD) (including idiopathic interstitial pneumonia [IIP], idiopathic pulmonary fibrosis [IPF], connective tissue disease [CTD], sarcoidosis) at least 6 months prior to Screening.
    c. Male and female participants must use contraceptives that are consistent with local regulations regarding the methods of contraception for those participating in clinical studies.
        i. Male participants:
            1. Male participants who are not sterile, with female partners of childbearing potential, must be using effective contraception from Day 1 to at least 90 days after the last dose of study drug.
            2. Male participants with women of child bearing potential (WOCBP) partner must use a condom in order to avoid potential exposure to embryo/fetus.
        ii. Female participants:
            1. Women must be postmenopausal (defined as no menses for 12 months without an alternative medical cause), surgically sterile, (ie, post-tubal ligation for at least 12 months) or using highly effective contraception methods (ie, methods that alone or in combination achieve <1% unintended pregnancy rates per year when used consistently and correctly) from Day 1 to at least 90 days after the last dose of study drug.
            2. Capable of giving signed informed consent that includes compliance with the requirements and restrictions listed in the ICF and in this protocol.

2. Exclusion Criteria:
    a. Primary diagnosis of chronic obstructive pulmonary disease (COPD).
    b. Allergy, or documented hypersensitivity or contraindication to TPIP or treprostinil (TRE) or mannitol (an excipient of the TPIP formulation).

c. Received or currently treated with riociguat, endothelial receptor antagonists, selexipag, phosphodiesterase 5 (PDE5) inhibitors and/or prostacyclin analogues within 30 days prior to Screening.
d. Started therapy with pirfenidone or nintedanib < 90 days prior to Screening, OR, if already receiving either medication, there is a dose change within 30 days of Screening Visit
e. Any known ventricular or supraventricular tachyarrhythmia (except for paroxysmal atrial fibrillation), and/or any symptomatic bradycardia.
f. History of heart disease including left ventricular ejection fraction (LVEF) ≤ 40% or clinically significant valvular, constrictive, or symptomatic atherosclerotic heart disease (eg, stable angina, myocardial infarction, etc).
g. Participation in a cardiopulmonary rehabilitation program within 30 days of the first Screening Visit.
h. Acutely decompensated heart failure within 30 days of Screening Visit.
i. Active and current symptomatic COVID-19 and/or previous diagnosis of moderate to severe disease, or hospitalization due to COVID-19
j. Supplemental oxygen requirement > 10L/min at Screening.
k. Exacerbation of underlying lung disease or active pulmonary or upper respiratory infection within 30 days of the first dose of study drug (may be rescreened at appropriate time).
l. Current or recent (past 30 days) lower respiratory tract infection (may be rescreened at appropriate time).
m. Any form of congenital heart disease or congenital heart defect (repaired or unrepaired) other than a patent foramen ovale.
n. History of alcohol or drug abuse within 6 months prior to Screening.
o. Current use of cigarettes (as defined by Center for Disease Control (CDC)) or e-cigarettes
p. Participants who currently inhale marijuana (recreational or medical).
q. Acute or chronic impairment (other than dyspnea), limiting the ability to comply with study requirements, in particular with 6-minute walk test (6MWT) (eg, angina pectoris, claudication, musculoskeletal disorder, need for walking aids).