Study to Evaluate Sotatercept (MK-7962) in Children With Pulmonary Arterial Hypertension (PAH) (MK-7962-008)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria

- Documented, historic diagnostic right heart catheterization (RHC) any time before Screening confirming the diagnosis of PAH WHO Group 1 in any of the following subtypes:
- Idiopathic pulmonary arterial hypertension (IPAH)
- Heritable PAH
- Drug/toxin-induced PAH
- PAH associated with connective tissue disease
- PAH-congenital heart disease (CHD) with shunt closure >6 months before Screening and subsequently confirmed by RHC before Screening
- PAH with coincidental shunt.
- Must be on a stable dose(s) of background PAH therapy (phosphdiesterase-5 (PDE5) inhibitors, endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulators (sGCS), or prostanoids [including subcutaneous and intravenous])
- If male, agree to the following during the intervention period and for at least 16 weeks (112 days) after the last dose of study intervention:
- Abstains from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agrees to remain abstinent or
- Uses contraception unless confirmed to be azoospermic (vasectomized or secondary to medical cause, documented from the site personnel's review of the participant's medical records, medical examination, or medical history interview) as detailed below:
- Uses a male condom plus partner use of an additional contraceptive method when having penile-vaginal intercourse with a woman of childbearing potential (WOCBP) who is not currently pregnant Note: Men with a pregnant or breastfeeding partner must agree to remain abstinent from penile-vaginal intercourse or use a male condom during each episode of penile-vaginal penetration.
- If female, must be either not a WOCBP or use a contraceptive method that is highly effective or be abstinent from heterosexual intercourse during the intervention period and for at least 16 weeks (112 days) after the last dose of study intervention
- If male, agrees to refrain from donating blood or sperm for the duration of the study and for 16 weeks (112 days) after the last dose of study intervention
- If female, agrees to refrain from donating blood, eggs, or ovum for the duration of the study and for at least 16 weeks (112 days) after the last dose of study intervention

Exclusion Criteria

- History of left-sided heart disease, including valvular disease (eg, moderate or greater mitral or aortic regurgitation or stenosis), left ventricular outflow tract obstruction, and/or left heart failure (eg, restrictive or dilated cardiomyopathy)
- Severe (as based on the opinion of the investigator) congenital or developmental abnormalities of the lung, thorax, and/or diaphragm
- History of Eisenmenger syndrome, Potts shunt, or atrial septostomy
- Unrepaired or residual cardiac shunt
- Diagnosis of pulmonary veno-occlusive diseases, pulmonary capillary hemangiomatosis, or overt signs of capillary and/or venous involvement
- PAH associated with portal hypertension
- Known visceral (lung, liver, or brain) arteriovenous malformation(s)
- History of full or partial pneumonectomy
- Untreated more than mild obstructive sleep apnea
- History of known pericardial constriction
- Family history of sudden cardiac death or long QT syndrome
- Any current or prior history of symptomatic coronary disease (myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft surgery, or cardiac anginal chest pain) within 6 months before Screening
- Cerebrovascular accident within 3 months before Screening
- Prior exposure to sotatercept or luspatercept or has had an allergic reaction to any of their excipients

Conditions & Interventions

Interventions:
DRUG: Sotatercept
Conditions:
Pulmonary Arterial Hypertension

More Information

Description:
The primary objectives of the study are to evaluate the safety and tolerability, and pharmacokinetics (PK) of sotatercept over 24 weeks of treatment in children ≥1 to \<18 years of age with PAH World Health Organization (WHO) Group 1 on standard of care (SoC). There is no formal hypothesis.

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