# Efficacy, Safety, and Pharmacokinetics of Vericiguat in Pediatric Participants With Heart Failure Due to Left Ventricular Systolic Dysfunction (MK-1242-036)

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 29 days to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Has symptomatic chronic heart failure (HF) resulting from systemic left ventricular (LV) systolic dysfunction.
- Has biventricular physiology with a morphologic systemic left ventricle.
- Is currently receiving stable medical therapy for HF.
- Has left ventricular ejection fraction (LVEF) <45% assessed within 3 months before randomization.
- Is of any sex/gender, from >28 days to <18 years of age inclusive. Must weigh ≥3 kg to participate.
- Female is eligible to participate if not pregnant or breastfeeding, and at least one of the following: is not a participant of childbearing potential (POCBP); or is a POCBP who uses a highly effective contraceptive method; has a negative highly sensitive pregnancy test; abstains from breastfeeding during the study intervention period and for at least 30 days after study intervention; and their medical history; their menstrual history, and recent sexual activity has been reviewed.
- Extension Period: Was randomized, received at least 1 dose of study intervention (vericiguat or placebo), did not permanently discontinue study intervention, and completed the Week 52 visit and safety follow-up period of the Base Period

Exclusion Criteria:

- Is clinically unstable-with at least one of the following: has symptomatic hypotension or is hypotensive for age, recent use of intravenous (IV) inotrope and/or IV vasodilator, or recent IV diuretic.
- Has a known allergy or sensitivity to vericiguat, any of its constituents, or any other soluble guanylate cyclase (sGC) stimulator.
- Has a history of single ventricle heart disease or has a morphologic systemic right ventricle.
- Has undergone heart transplantation, is awaiting heart transplantation United Network for Organ Sharing (UNOS) Class 1A or equivalent, is receiving continuous IV infusion of an inotrope, or has an implanted ventricular assist device.
- Has sustained or symptomatic dysrhythmia uncontrolled with drug or device therapy.
- Has had recent cardiovascular (CV) surgical procedure or percutaneous intervention to palliate or correct congenital CV malformations.
- Has unoperated or residual hemodynamically significant congenital cardiac malformations.
- Has hypertrophic or restrictive cardiomyopathy.
- Has active myocarditis or has been recently diagnosed with presumed or definitive myocarditis.
- Has acute coronary syndrome, undergone recent coronary intervention, or indication for coronary revascularization.
- Has symptomatic carotid stenosis or other symptomatic cerebrovascular disease
- Has severe pulmonary hypertension.
- Requires continuous home oxygen for significant pulmonary disease and/or has known interstitial lung disease.
- Has severe chronic kidney disease.
- Has hepatic disorder such as hepatic encephalopathy, hepatic laboratory abnormalities or Child Pugh Class C.
- Has a gastrointestinal or biliary disorder that could impair absorption, metabolism, or excretion of medications.
- Has significant bone disease (other than osteopenia) that in the assessment of the investigator can alter bone formation
- Has concurrent or anticipated concomitant use of phosphodiesterase type 5 inhibitors or an sGC stimulator.
- Has received a COVID-19 vaccination within 1 week before randomization.

## Conditions & Interventions

Interventions:
DRUG: Vericiguat tablet, DRUG: Vericiguat suspension, DRUG: Placebo tablet, DRUG: Placebo suspension
Conditions:
Heart Failure, Left Ventricular Systolic Dysfunction

## More Information

Description:
This study aims to compare the efficacy of vericiguat versus placebo on change in n-terminal pro-brain natriuretic peptide (NTproBNP) from baseline to Week 16 of the Base Period. The primary hypothesis is that vericiguat is superior to placebo in reducing NT-proBNP at Week 16 of the Base Period

Contact(s): Sarah Speed - sarah.speed@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT05714085

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