



Exploratory Study of Danicamtiv in Patients With Primary Dilated Cardiomyopathy (DCM) Due to Genetic Variants

CLINICALTRIALS.GOV IDENTIFIER
NCT04572893

RECRUITMENT STATUS
RECRUITING

FIRST POSTED
OCTOBER 1, 2020

LAST UPDATE POSTED
NOVEMBER 19, 2021

STUDY DESCRIPTION

Brief Summary

The purpose of this Phase 2a study is to establish safety and preliminary efficacy of treatment with danicamtiv in patients with primary dilated cardiomyopathy (DCM) due to MYH7 or TTN variants .

Condition or Disease: Primary Familial Dilated Cardiomyopathy

Intervention/treatment: Drug: danicamtiv

Phase: Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type:	Interventional	Actual Study Start Date:	August 2020
Estimated Enrollment :	24 participants	Estimated Primary Completion Date:	March 2022
Intervention Model :	Sequential Assignment	Estimated Study Completion Date:	March 2024
Masking:	None (Open Label) ()		
Primary Purpose:	Treatment		
Official Title:	An Open-Label, Exploratory Study of the Safety and Preliminary Efficacy of Danicamtiv in Stable Ambulatory Patients With Primary Dilated Cardiomyopathy Due to Either MYH7 or TTN Variants		

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: MYK-491 Primary DCM due to MYH7 or TTN Variant	Drug: danicamtiv Myosin activator

OUTCOME MEASURES

Primary Outcome Measures: 1. Frequency and severity of treatment-emergent adverse events and serious adverse events. [Time Frame: Up to 22 days, optional extension of up to 96 weeks]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 80 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Has stable primary dilated cardiomyopathy due to either MYH7 or TTN variant Has adequate acoustic windows for echocardiography Maximum of 3 family members with same variant can be enrolled

Exclusion Criteria:

Significant structural cardiac abnormalities including valvar dysfunction on Screening transthoracic echo(s) A pathogenic variant implicated in DCM of another gene other than MYH7 or TTN Routinely scheduled outpatient intravenous (IV) infusions for heart failure (e.g., inotropes, afterload reduction, or diuretics)

Presence of protocol specified laboratory abnormalities at Screening Recent acute coronary syndrome or angina pectoris (<90 days) Recent hospitalization for heart failure (<90 days)

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Medical Information (Use email contact) clinical.trials@bms.com

Locations

United States, California	University of California, San Diego Medical Center	La Jolla
United States, District of Columbia	MedStar Georgetown University Hospital	Washington
United States, Florida	University of South Florida	Tampa
United States, Illinois	Northwestern Medical Faculty Foundation	Chicago
United States, Massachusetts	Brigham and Women's Hospital	Boston
United States, Minnesota	Mayo Clinic - Rochester	Rochester
United States, Ohio	Cleveland Clinic	Cleveland
United States, Ohio	Ohio State University Medical Center	Columbus
United States, Pennsylvania	University of Pennsylvania - Heart and Vascular Center	Philadelphia
United States, South Carolina	Medical University of South Carolina	Charleston
United States, Tennessee	The Stern Cardiovascular Center	Germantown
United States, Texas	Austin Heart	Austin
Germany	Universitaetsklinikum Heidelberg	Heidelberg
Germany	Universitaetsklinikum Würzburg	Würzburg
Spain, Madrid	Hospital Universitario Puerta de Hierro Majadahonda	Majadahonda
Spain, Murcia	Hospital Clinico Universitario Virgen de la Arrixaca	El Palmar
Spain	Complejo Hospitalario Universitario A Coruña	A Coruña
United Kingdom	St. Bartholomew's Hospital	London
United Kingdom	Royal Brompton Hospital	London

Sponsors and Collaborators

MyoKardia, Inc.

Investigator

MORE INFORMATION

Responsible Party :	MyoKardia, Inc.
ClinicalTrials.gov Identifier :	NCT04572893
Other Study ID Numbers :	MYK-491-006, 2019-003626-24
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Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by MyoKardia, Inc.:	Primary dilated cardiomyopathy (DCM) Familial dilated cardiomyopathy (DCM) Myosin Heavy Chain 7 (MYH7) Titin (TTN) MYK-491 danicamtiv
Additional relevant MeSH terms :	Cardiomyopathies Cardiomegaly Cardiomyopathy, Dilated Laminopathies Heart Diseases Genetic Diseases, Inborn Cardiovascular Diseases