MyPEAK™-1 CLINICAL TRIAL

for *MYBPC3*-associated HCM

The MyPEAK-1 clinical trial will research a gene therapy called TN-201 for the treatment of hypertrophic cardiomyopathy (HCM) caused by mutations (changes) in the *MYBPC3* gene. Changes in the *MYBPC3* gene can prevent heart muscles from making enough protein to enable the heart to pump as expected. This can cause *MYBPC3*-associated HCM.

WHAT IS TN-201?

TN-201 is an investigational gene therapy designed to reach the specific muscle cells that make the heart contract and relax with each beat.

- TN-201 uses an adeno-associated virus (AAV) to deliver a working *MYBPC3* gene to the muscle cells in the heart
- Once in these cells, TN-201 may help make the protein needed to restore typical heart function so the heart can pump as expected
- TN-201 is given as a one-time intravenous (IV) infusion

AAV is one type of virus commonly used as a capsid (also called a vector) because it is efficient at delivering new genes to cells and is not known to cause symptoms or diseases in people.[1]

There are different types of AAV capsids. The AAV9 capsid used in TN-201 is the most extensively studied and is proven to reach heart muscle cells.[2,3]

WHAT IS THE PURPOSE OF THE MyPEAK-1 CLINICAL TRIAL?

MyPEAK-1 is a Phase 1b clinical trial. This means it is the first trial to study TN-201 in humans. The goals are to understand:

- The safety of TN-201 in humans
- Any potential side effects
- The best dose of TN-201
- The effects of TN-201 on the body

The MyPEAK-1 clinical trial will also look at how TN-201 affects overall health and quality of life based on feedback from participants and their doctors.

AAV gene therapy does carry some risk. Ask your doctor about the known risks of AAV gene therapy.

WHO CAN TAKE PART IN THE MyPEAK-1 CLINICAL TRIAL?

The MyPEAK-1 clinical trial will enroll a limited number of people in the United States. To be in the trial, a person must:

- Be 18 to 65 years old
- Have HCM caused by mutations in the *MYBPC3* gene
- Have mild or moderate heart failure symptoms limiting daily activities
- Have a low level of antibodies to the AAVs

These are not all of the eligibility criteria. Clinical trial staff will evaluate interested people and determine if they are eligible to take part in MyPEAK-1.

WHAT TO EXPECT IN THE MyPEAK-1 CLINICAL TRIAL

MAIN CLINICAL TRIAL		
8-12 Weeks	Informed Consent & Screening	• 1 visit to gather information about a person's health to determine whether a person can participate • Informed consent to ensure a person understands: ◦ The purpose of the clinical trial ◦ All participants will receive TN-201, the investigational gene therapy ◦ The expectations for participation, including required visits, procedures, and tests ◦ Potential risks and benefits ◦ Options for leaving the clinical trial if desired
	Pre-Treatment Activities	• The clinical trial doctor will start the participant on medicines that suppress the immune system before receiving TN-201 ◦ The doctor will review the reason these medicines are needed, when these medicines will be stopped, and any potential side effects • The doctor will gather additional information about the participant's health using a blood test, three heart/exercise tests and other assessments
About 8 Days	Hospitalization for Infusion of TN-201 & Monitoring	• The infusion of TN-201 typically takes 2 to 4 hours • Hospitalization for eight days for close monitoring, management, and treatment of any possible side effects
About 1 Year	First Year Visits	• 19 visits over 1 year to monitor safety and changes in heart function and HCM symptoms*
LONG-TERM FOLLOW-UP		
About 4 Years	Follow-up Visits	• 5 visits total • Monitor safety and changes in heart function and HCM symptoms over time
TOTAL PARTICIPATION – ABOUT 5 YEARS		

**Most visits will be in person at the trial site with a select number of visits completed by phone or at a local lab.*

IF YOU ARE INTERESTED IN PARTICIPATING:

Talk to your doctor about whether you may be a candidate for this clinical trial

Visit ClinicalTrials.gov and enter identifier number NCT05836259 to learn more

Contact Tenaya at Patient.Advocacy@tenayathera.com to request more information

THE USE OF TN-201 DESCRIBED HERE IS INVESTIGATIONAL. SAFETY AND EFFICACY HAVE NOT BEEN ESTABLISHED. TN-201 HAS NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION OR ANY OTHER COUNTRY'S HEALTH AUTHORITY OR REGULATORY AGENCY.

REFERENCES 1. Li C, Samulski RJ. *Nat Rev Genet*. 2020;21(4):255-272. 2. Sasaki N, et al. *Heart Lung* Circ. 2023;32:816-824. 3. Novartis. https://www.novartis.com/sites/novartis_com/files/q4-2022-investor-presentation.pdf. Accessed April 9, 2024.

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