MAGNITUDE: A Phase 3 Study of NTLA-2001 in Participants With Transthyretin Amyloidosis With Cardiomyopathy (ATTR-CM)

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 90 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Documented diagnosis of ATTR amyloidosis with cardiomyopathy * Medical history of heart failure (HF) * Symptoms of HF are optimally managed and clinically stable within 28 days prior to administration of study intervention * Screening NT-proBNP, a blood marker of HF severity, greater than or equal to 600 pg/mL and less than 10,000 pg/mL

Exclusion Criteria:

* New York Heart Association (NYHA) Class IV HF * Polyneuropathy Disability score of IV (confined to wheelchair or bed) * Has hepatitis B, hepatitis C or human immunodeficiency virus (HIV) infection * History of active malignancy within 3 years prior to screening * RNA silencer therapy (patisiran, inotersen and/or eplontersen) within 12 months prior to dosing. Any prior vutrisiran use is not allowed * Initiation of tafamidis or accoramidis within 56 days prior to study dosing * Estimated glomerular filtration rate (eGFR) \<30 mL/min/1.73m\^2 * Liver failure * Uncontrolled blood pressure * Unable or unwilling to take vitamin A supplementation for the duration of the study

Conditions & Interventions

Interventions:

BIOLOGICAL: NTLA-2001, DRUG: Placebo

Conditions:

Transthyretin Amyloidosis (ATTR) with Cardiomyopathy

Keywords:

TTR, Amyloidosis, Cardiomyopathy, NTLA-2001, ATTR-CM, Transthyretin, ATTR, TTR-mediated amyloidosis, Amyloidosis, Hereditary, Amyloidosis, Hereditary, Transthyretin-Related Amyloidosis, Transthyretin amyloid cardiomyopathy, TTR cardiomyopathy, Wild-type TTR, V122I, Amyloidosis, Wild Type

More Information

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Principal Investigator: Phase: PHASE3

IRB Number:

System ID: NCT06128629

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