

MT2024-42: Phase 1b Dose Expansion/2 Study of NXC-201 for the Treatment of Patients with Relapsed or Refractory AL Amyloidosis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- walking and able to do selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - proven diagnosis of systemic AL amyloidosis
- have symptoms of organ involvement (heart, kidney, liver/GI tract, peripheral nervous system) - able to swallow pills - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- prior treatment with CAR T therapy - stroke or seizure within past 6 months - significant heart disease - women who is pregnant, or breastfeeding, or planning to become pregnant - unwilling to practice effective birth control - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:

Cancer, Rare Diseases

Keywords:

Clinics and Surgery Center (CSC), CAR-T, Light Chain (AL) Amyloidosis

More Information

Description: The purpose of this study is to find the best dose of NXC-201 to treat AL amyloidosis. The people in this study have AL amyloidosis that came back or does not get better with treatment. NXC-201 is a cellular therapy made from your own white blood cells called T cells. If you join this study, we will collect some of your T cells and modify (change) them in a lab. This modification will help your T cells find and kill abnormal plasma cells. These genetically changed T cells are called chimeric antigen receptor (CAR) T cells. NXC-201 is a CAR T cell therapy and is given intravenously (by vein). To prepare your body for NXC-201, you will also get fludarabine and cyclophosphamide, which are chemotherapy drugs. After you get NXC-201, you will be in the hospital for at least 10 days.

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Phase: PHASE1

IRB Number: STUDY00024366

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