Safety and Efficacy Study of Intracystic TARA-002 for the Treatment of Lymphatic Malformations in Participants 6 Months to Less Than 18 Years of Age

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 months to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Male or female participants 6 months to less than 18 years of age at the time of informed consent/assent form was signed
- Participants whose parent/LAR(s) have voluntarily given written consent and participants who provided assent (if applicable) after the study has been explained to them
- Participants with macrocystic LM or mixed cystic LM (≥ 50% macrocystic disease measured by volume) of the Head/Neck/Mediastinum according to the ISSVA 2018 criteria (ISSVA 2018) measured via LM imaging at Screening to confirm, upon central review, the diagnosis of macrocystic or mixed cystic LM
- Participants who may have had surgical or sclerotherapy treatment for their LM, but not within six months of the consent/assent form being signed

Exclusion Criteria:

- Penicillin allergy
- Vascular tumors or combined vascular malformations
- Microcystic LM or mixed cystic LM with predominant microcystic features
- LMs of the orbit (orbital LM) as target cyst

For more information on eligibility criteria, please contact the sponsor.

Conditions & Interventions

Interventions:
BIOLOGICAL: TARA-002
Conditions:
Lymphatic Malformation
Keywords:
Macrocystic lymphatic malformations, Mixed-cystic lymphatic malformations

More Information

Description:
This is a Phase 2a/b single arm open label study to evaluate the safety, reactogenicity, and efficacy of intracystic injection of TARA-002 in participants 6 months to less than 18 years of age for the treatment of macrocystic and mixed cystic lymphatic malformations. The Phase 2a safety lead-in, age de-escalation study is designed to establish the safety of TARA-002 in older participants 6 years to less than 18 years before proceeding to younger participants 2 years to less than 6 years, then 6 months to less than 2 years. The Phase 2b is an expansion study in which enrollment of participants will be initiated after safety has been established in each cohort during the Phase 2a safety lead-in study. Each participant will receive up to 4 injections of TARA-002 spaced approximately 6 weeks apart.

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IRB Number:
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