STARBORN-1: Interim Efficacy and Safety Data in Pediatric Participants with Macrocystic and Mixed-Cystic Lymphatic Malformations Treated with Intracystic Injection of TARA-002

Jesse Jones[1], Claire Kaufman[2], Jason S. Park[3], James Phillips[3], Christopher Baron[3], Taizo A. Nakano[4], David Darrow[5], Scott Davis[6], Gresham Richter[7], Adrienne Hammill[8], Jacqueline Zummo[9], Khushboo Belani[9], Claire Middleton[9], Bruce Reidenberg[10], Eppie Brown[9], McKenna Metcalf[9], Soan Kim[9], Chen Quin Lam[11], Nancy Bauman[12]

[1]Children's Hospital of Alabama, Birmingham, AL; [2]Oregon Health & Science University, Portland, OR; [3]Vanderbilt University Medical Center, Nashville, TN; [4]Children's Hospital Colorado, Aurora, CO; [5]Eastern Virginia Medical School, Norfolk, VA; [6]Nemours Children's Clinic – Jacksonville, Jacksonville, FL; [7]Arkansas Children's Hospital/UAMS, Arkansas, Little Rock, AR; [8]Cincinnati Children's Hospital Medical Center, Cincinnati, OH; [9]Protara Therapeutics, Inc., New York, NY; [10]Weill Cornell Medicine, New York, NY; [11]Pharmapace Inc. San Diego, CA; [12]Children's National Medical Center: Children's Research Institute, Washington, D.C.

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Contact: clinicaltrials@protaratx.com

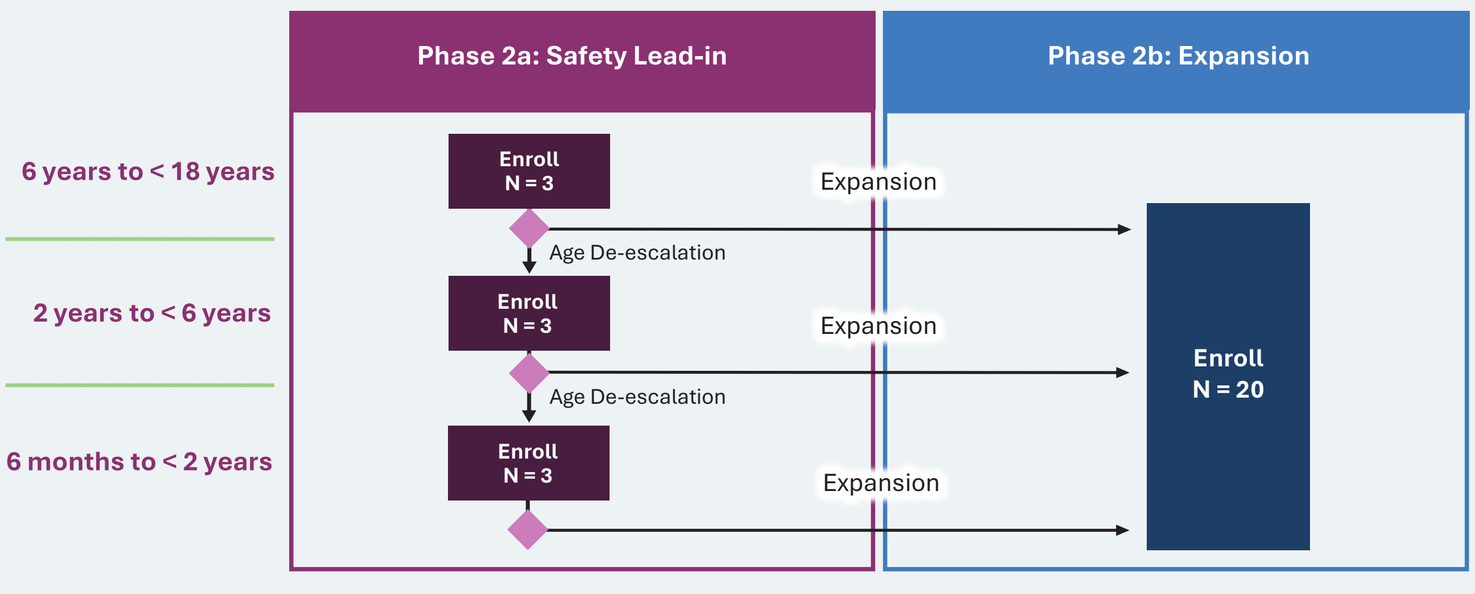
PURPOSE

- Lymphatic malformations (LMs) are rare, potentially life-threatening congenital malformations of lymphatic vessels.
  - Most LMs are known to progress without intervention, resulting in functional impairment and disfigurement.
- TARA-002 is an inactivated, genetically distinct strain of *Streptococcus pyogenes* (A group, type 3) Su strain, being developed for the treatment of macrocystic and mixed-cystic LMs (i.e., macrocystic and microcystic).
- TARA-002 is developed from the same master cell bank as OK-432, which has been a standard of care for LMs in Japan and Taiwan for over 30 years.
- TARA-002 is administered locally and induces a strong immune response cascade.
  - This increases lymph flow, accelerates lymphatic drainage, and shrinks the cystic space via fibrotic adhesion.

METHODS

- STARBORN-1 (NCT05871970) is an ongoing, actively enrolling Phase 2a/b single-arm, open-label study assessing the safety, reactogenicity, and efficacy of TARA-002 in participants 6 months to <18 years with macrocystic and mixed-cystic LMs.
  - Phase 2a is a safety lead-in, age de-escalation study.
  - Phase 2b is an expansion study.
- Participants received up to four injections of TARA-002 every 6 weeks.
- Efficacy is assessed via central imaging (MRI or CT) or via Investigator assessment (physical exam, visual inspection and ultrasound) at 8-weeks post-treatment.
  - Clinical success is defined as the proportion of participants who demonstrate a complete (90-100% reduction) or substantial (60-90% reduction) response of the cyst volume from baseline.
- Durable response is assessed at 32-weeks post-treatment.
- Clinical and laboratory safety is monitored throughout the study.
- The data cutoff date is 10-Apr-2026.

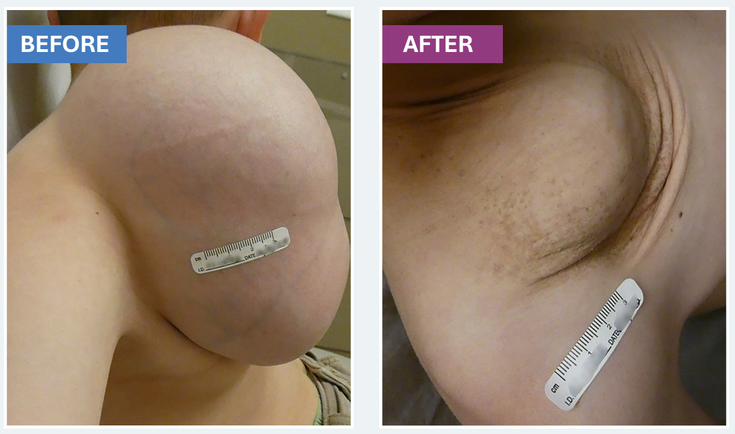
STARBORN-1 STUDY SCHEMA



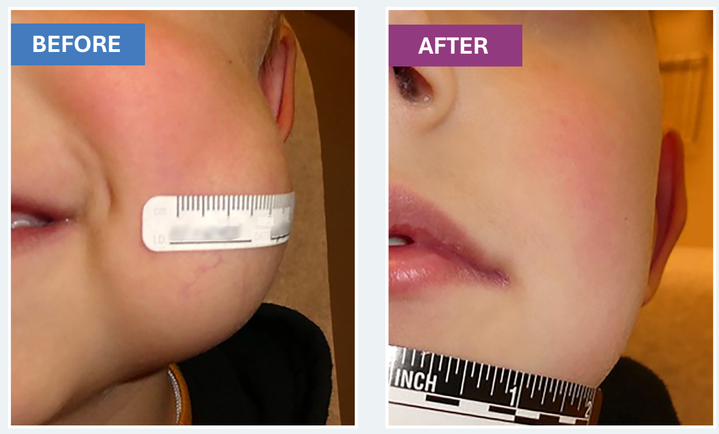
NOTES: During the Phase 2a safety lead-in, the Sponsor may allow for up to 6 participants to be enrolled to account for potential misdiagnosis or drop-outs. The Data Monitoring Committee (DMC) is responsible for recommendation on age de-escalation and expansion.

RESULTS

MEDICAL PHOTOGRAPHY FROM 2 PARTICIPANTS PRE-TREATMENT AND 8-WEEKS POST-TREATMENT WITH TARA-002 IN STARBORN-1 TRIAL



Baseline 1,739mL macrocystic LM received 4 injections of TARA-002 (20mL [1], 20mL [2], 19mL [3], 1mL [4]); 8 years of age.



Baseline 58mL macrocystic LM received 2 injections of TARA-002 (20mL [1], 17mL [2]); 5 years of age.

STARBORN-1 DEMOGRAPHICS AND BASELINE CHARACTERISTICS

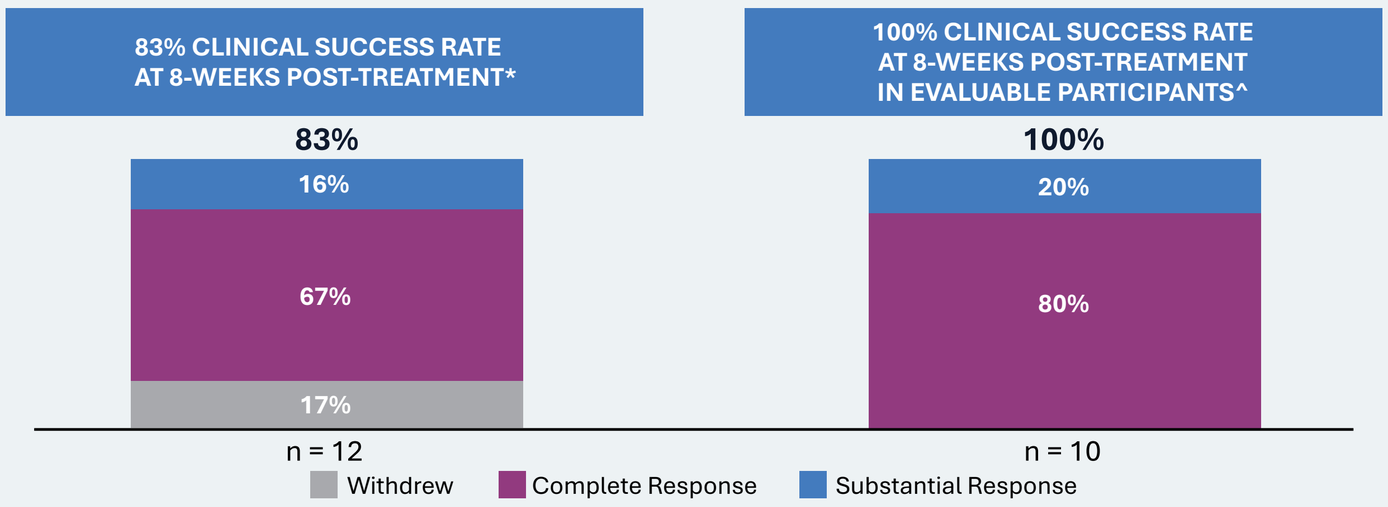
N = 16	
Age, median (min, max)	5.0 (1, 15)
Sex, female, n (%)	8 (50.0)
Race, white, n (%)	11 (68.8)
Ethnicity, not Hispanic, n (%)	12 (75.0)
LM Type, n (%)	
Macrocystic	14 (87.5)
Mixed-cystic	2 (12.5)

TARA-002 DEMONSTRATED A FAVORABLE SAFETY PROFILE AND WAS WELL-TOLERATED IN PARTICIPANTS WITH LMs

N = 16	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
TEAEs, n (%)	11 (69)	11 (69)	9 (56)	1 (6)	0 (0)
Related TEAEs, n (%)	10 (63)	10 (63)	7 (44)	1 (6)	0 (0)
AESIs, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Serious TEAEs, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
MAAEs, n (%)	6 (38)	3 (19)	5 (31)	1 (6)	0 (0)
Related TEAEs leading to study drug withdrawal, n (%)	1 (6)	0 (0)	1 (6)	0 (0)	0 (0)

AESI = adverse event of special interest; MAAE = medically attended adverse event; TEAE = treatment emergent adverse event

TARA-002 DEMONSTRATED CLINICAL SUCCESS IN 83% OF PARTICIPANTS WITH COMPLETE FOLLOW UP TREATMENT AND IN 100% OF EVALUABLE PARTICIPANTS WITH LMs



*Includes participants who received at least one intracystic injection of the study intervention. Excludes 3 participants who are still in treatment and one whose post-treatment assessment is pending.

^Includes participants who completed the 8-week post-treatment assessment. 2 participants withdrew from the study before 8-week post-treatment assessment; 1 participant was mis-diagnosed, had a rare form of cancer, and did not respond to treatment; 2 participants were mis-diagnosed and had ranula; 1 participant dropped out after achieving a marked resolution of the LM.

Data cutoff: 10-Apr-2026

- To date, 16 participants (median age: 5 years) were enrolled and treated with TARA-002.
  - The majority of participants had macrocystic LM at baseline (87.5%, 14/16).
- Participants received an average of 2 injections of TARA-002.
- 83% (10/12) of participants that completed treatment achieved clinical success/clinical improvement.
- 100% (10/10) of the evaluable participants achieved clinical success/clinical improvement at 8-week post-treatment assessment.
  - Clinical success was achieved with one or two doses of TARA-002 in 80% of participants.
  - 7 participants have reached the 32-week post-treatment assessment and remain disease-free.
- Local and systemic reactions were easily managed.
- TEAEs were generally mild to moderate and commonly included swelling and fatigue.
- There were no serious TEAEs or AEs of special interest.

CONCLUSIONS

- TARA-002 demonstrated encouraging efficacy with clinically meaningful improvement in treated LMs and was well-tolerated.
- These findings support the continued development of TARA-002 in LMs and are consistent with the established safety and efficacy profile of OK-432.

DISCLOSURES

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