

TARA-002 in Lymphatic Malformations: Targeted Therapy for a Significant Unmet Need

May 19, 2026

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Agenda

Welcome and Introduction



Jesse Shefferman
Co-founder, Director,
Chief Executive Officer

The Unmet Need in Lymphatic Malformations (LMs)



Naiem Nassiri, MD
Vascular & Endovascular
Surgery, The Vascular Care
Group and Adjunct Faculty
at Yale School of Medicine

TARA-002 in LMs



Jacqueline Zummo, PhD
Co-founder, Senior Vice
President, Chief R&D
Officer

Case Studies with TARA-002 in LMs



Jesse G.A. Jones, MD
Associate Professor, Dept
of Neurosurgery and
Radiology at the University
of Alabama

LMs Market Overview



William Conkling
Chief Commercial Officer

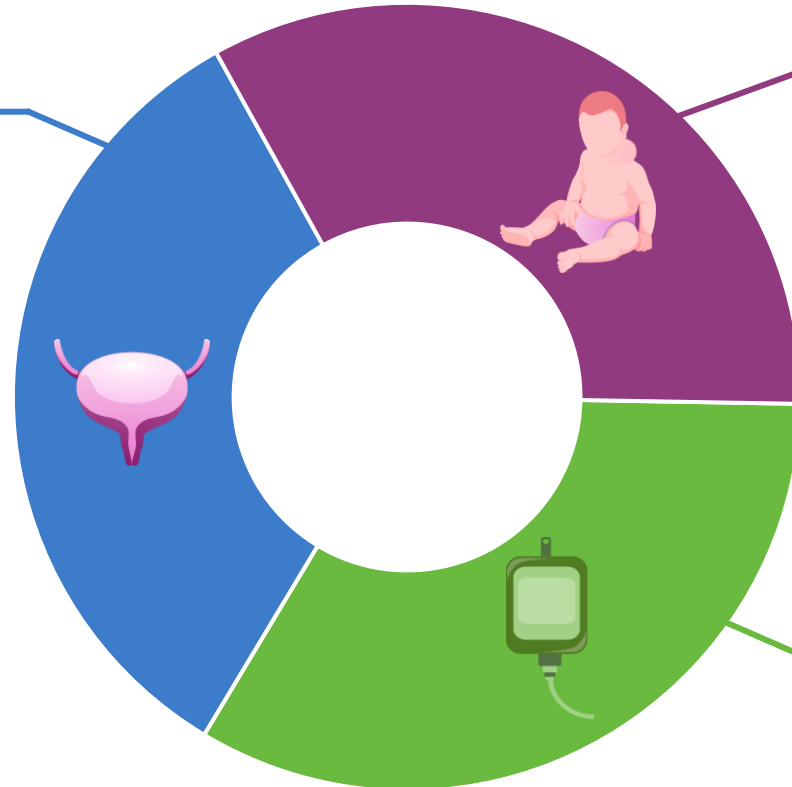
Q&A

Transformative Investigational Therapies in Oncology and Rare Disease

ONCOLOGY

TARA-002 in Non-Muscle Invasive Bladder Cancer

- Positive interim data in BCG-Unresponsive and BCG-Naïve patients from ADVANCED-2 trial of TARA-002 in NMIBC
- Plan to initiate ADVANCED-3, a registrational trial in BCG-Naïve patients in 2H'26
- Unique product characteristics anticipated to drive significant adoption in large market with high unmet need



RARE PEDIATRIC

TARA-002 in Lymphatic Malformations

- Pediatric program for indication with no currently approved therapies available in the US
- Positive interim data update from the STARBORN-1 trial assessing TARA-002 in pediatric LMs
- Intend to submit BLA in 2H'27
- Granted FDA Rare Pediatric Disease, Orphan Drug, Breakthrough Therapy and Fast Track designations

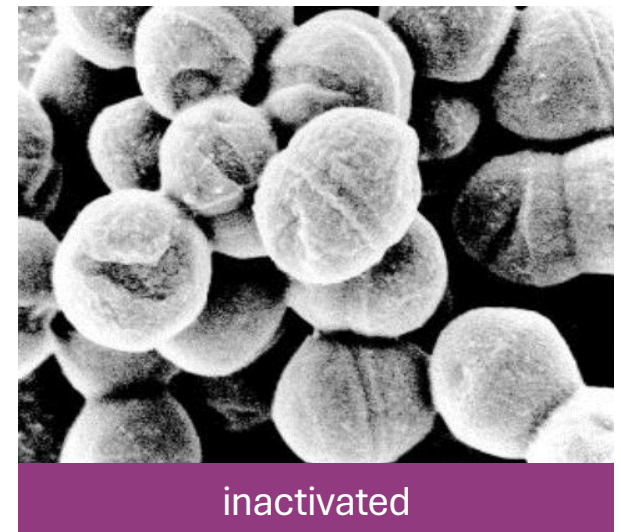
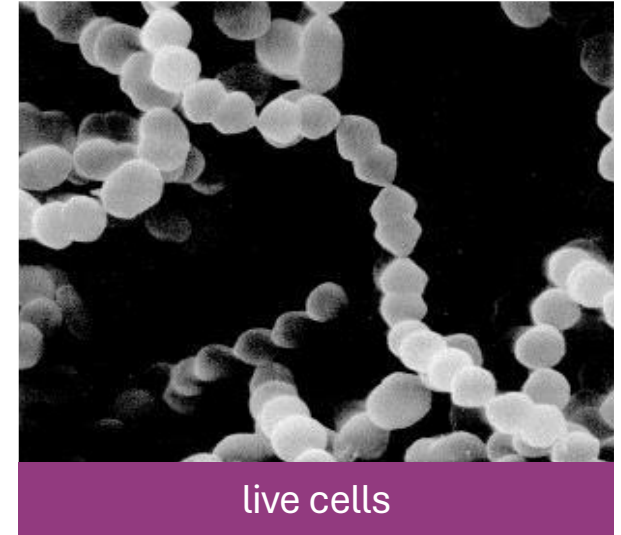
RARE GI

IV Choline Chloride for Patients on Parenteral Support

- 78% of patients dependent on PS are choline-deficient and the majority have resulting liver damage, yet no approved IV formulations exist
- Granted FDA Orphan Drug and Fast Track designations

TARA-002 in LMs: Built on the Deep History of OK-432 for the Treatment of LMs

- TARA-002 is an investigational, genetically distinct strain of *Streptococcus pyogenes* that is inactivated while retaining its immune-stimulating properties
- TARA-002 predecessor compound OK-432 is approved in Japan and has been the standard of care for LMs for 30+ years
- OK-432 has demonstrated safety and efficacy in over 500 pediatric LMs patients in University of Iowa led compassionate use program
- TARA-002 has been granted Rare Pediatric Disease, Orphan Drug, Breakthrough Therapy and Fast Track designations by the U.S. FDA and is eligible for a Priority Review Voucher (PRV)
- Historical literature and patient experience demonstrate that TARA-002 has the potential to treat other maxillofacial cysts
- Protara has worldwide rights ex-Japan & Taiwan for TARA-002/OK-432



Clear Regulatory Path for TARA-002 in LMs

Plan to submit a
BLA in **2H 2027**

- Review of TARA-002 for LMs has transitioned from the Office of Vaccines Research and Review to the Office of Therapeutic Products
- FDA will evaluate the risk-benefit profile of TARA-002 in LMs based on the results of the STARBORN-1 trial
- No additional trial required, no changes to current STARBORN-1 trial requested and confirmed current non-clinical package is complete

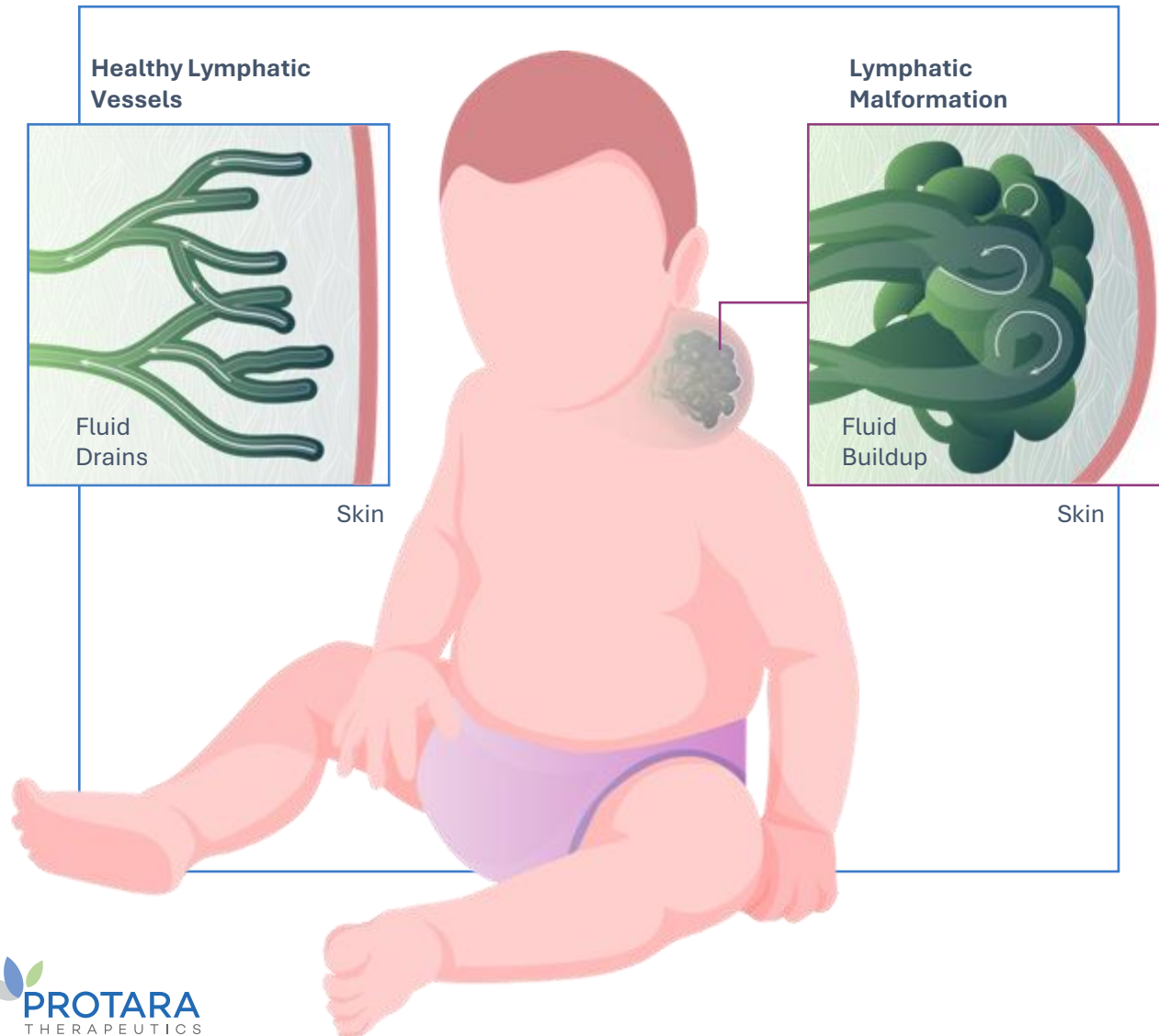


The Unmet Need in LMs

Naiem Nassiri, MD, FSVS, RPVI

Vascular & Endovascular Surgery, The Vascular Care Group (TVCG); Founding Director, TVCG CARES (Center for Anomalies & Rare Entities), International and Adjunct / Volunteer Faculty in Surgery (Vascular) Yale School of Medicine & Yale New Haven Hospital

LMs is a Significant Pediatric Rare Disease Opportunity with no Currently Approved Therapies



Lymphatic Malformations

- Rare, non-malignant, congenital malformations of lymphatic vessels resulting in the failure of these structures to connect or drain into the venous system
- Once diagnosed, physicians find that treatment is almost always warranted as LMs can cause significant morbidity affecting breathing, swallowing, feeding, and speaking

Three Distinct LMs Subtypes – Today’s Focus is on Macrocystic and Mixed Cystic LMs

Incidence: 1,500 cases per year¹

47%

Macrocystic LMs²



Large cysts >1-2 cm diameter, well-defined fluid-filled spaces

32%

Mixed Cystic LMs



Combination of both macrocystic and microcystic components

21%

Microcystic LMs



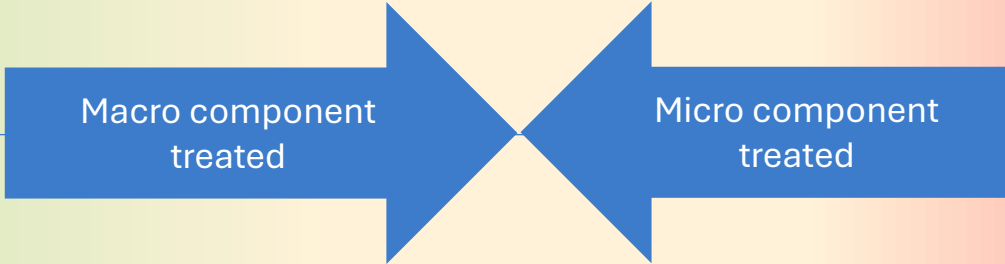
Small, infiltrative lesions with tiny cystic spaces

Current Treatment Paradigm

- Surgery
- Sclerotherapy

Available and Investigational Tx options

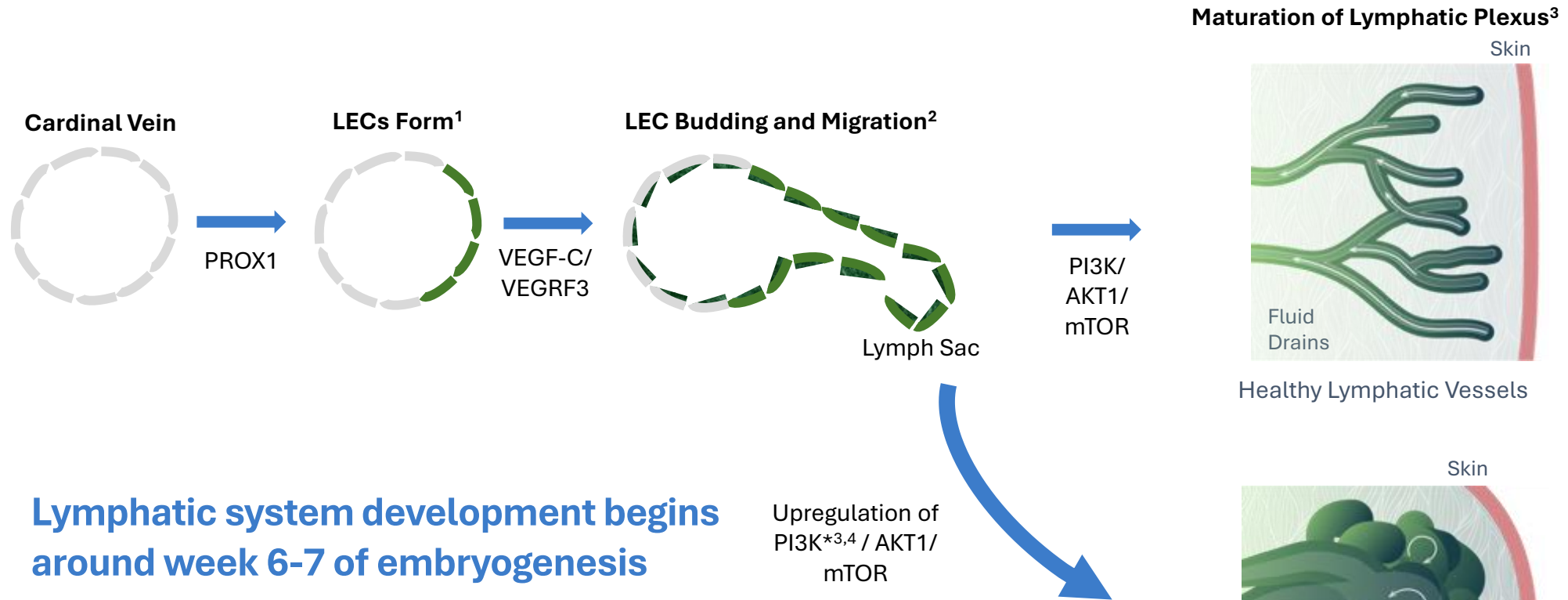
TARA-002



- Sclerotherapy
- Alpelisib

- QTORIN
- Zovegalisib

Developmental Biology & Pathophysiology of Lymphatic Malformations



*Due to PIK3CA mutation(s)

AKT1 = AKT serine/threonine kinase 1; mTOR = mechanistic target of rapamycin; LEC = lymphatic endothelial cells; PI3K = phosphoinositide 3-kinase

¹Lee SY, et al.. J Develop Biol. 2022;10(1):11.; ²Martinez-Corral I, et al.. Nature Comm. 2020;11:2869; ³Mäkinen T, et al. Circ Res. 2021;129:136-154; ⁴Blesinger H, et al.. PLoS One. 2018;13(7):e0200343

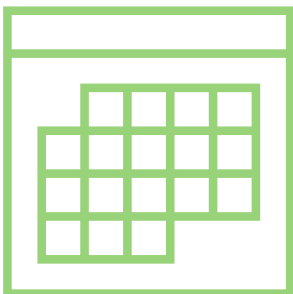
Natural History and Age of Diagnosis



NATURAL HISTORY OF LYMPHATIC MALFORMATIONS¹

- 75% are head and neck
- Grow proportionate with child but can suddenly expand, especially in adolescence
- Common complications: infections (cellulitis), pain, bleeding, and leakage of fluid from skin vesicles
- Severe complications: breathing difficulties (airway obstruction), swallowing problems, or vision loss

AGE OF DIAGNOSIS OF LYMPHATIC MALFORMATIONS^{2,3}



- Ultrasound detection possible in utero
- Approximately 50% apparent at birth and almost 90% diagnosed by 2 years
- Smaller, deeper cysts may not be identified until childhood, adolescence, or even adulthood

Disease Burden in Pediatric Patients



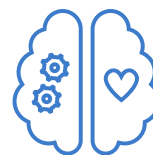
Physical Symptoms & Complications of LMs:

Bleeding, infections, discomfort/pain, and overgrowth of nearby tissue (nerves, muscle, bone)^{1,2}



Functional Impact:

Breathing difficulties, feeding/swallowing problems, and vision loss or decreased extraocular mobility³



Psychological and Social Quality of Life:

Children and their families experience decreased quality of life which worsens with age^{4,5}



Chronic Nature & Progression:

Congenital but often progressive, with a 40%+ risk of progression during childhood and an approximate 64% risk during adolescence⁶



Healthcare Utilization:

Requires long-term management, high rates of hospital utilization for treatment of infections and surgical interventions^{7,8}

¹Greene et al. Clin Plast Surg. 2011;38:75-82.; ²Defnet et al. Pediatr Surg Int. 2016;32:425-433; ³Elluru et al. Semin Pediatr Surg. 2014;23:178-185; ⁴Arleo TL, et al. J Pediatr Hematol Oncol. 2023;45(7):e847-e856; ⁵Ghaffarpour et al. Acta Paediatr. 2018 Dec 17. doi: 10.1111/apa.14700; ⁶Hassanein AH, et al. J Craniofac Surg. 2012;23(1):149-152; ⁷Cheng J, et al. Lymphat Res Biol. 2017;15(3):241-245; ⁸Ma et al. Pediatr Radiol. 2017;47:566-573

Current Management Approaches for Macrocystic LMs

Current treatment is multimodal:

UNMET NEED

No FDA-approved therapies exist for the treatment of lymphatic malformations^{1,2}

→ Sclerotherapy or Intralesional ablation

Injection with chemicals or chemotherapeutic agents to collapse the cyst with limited evidence of efficacy³

→ Surgical excision

Resection or debulking of the lesion

✘ Topical / systemic therapies

Generally not used in the Macrocystic LMs setting

Sclerotherapy Techniques and Limitations



Ablative Agents and Potential Side Effects

- Ethanol – high complication rates, including blistering, hemoglobinuria, deep ulceration, nerve injury and the potential for serious side effects, including central cardiopulmonary toxicity, and death^{1,4-8}
- Bleomycin – systemic absorption, pulmonary fibrosis, and death^{1,2,5,7,8}
- Doxycycline – Acute pain, permanent discoloration of the teeth⁷



Efficacy Limitations

- Limited well-controlled clinical data and guidelines and no standardization of dosing regimens
- Treatments are rarely curative with potential for recurrence of the LM
- Differential efficacy outcomes
- General anesthesia requirement for some injections, which is not ideal for young patients⁵

¹Nassiri et al. J Vasc Surg Venous Lymphat Disord. 2016; 4(2):p257-265; ²Elluru et al. Pediatr Surg. 2014;23:178-185; ³DeMaria et al. J Vasc Surg Venous Lymphat Disord. 2020;8(1):154-164; ⁴Burrows et al. Lymphat Res Biol. 2008;6: 209-216; ⁵Muir et al. Pediatr Surg Int. 2004;20:23-27; ⁶Alomari et al. J Vasc Interv Radiol. 2006;17(10):1639-1648; ⁷Ha et al. Curr Pediatr Rev. 2014;10(3):238-248; ⁸Orvidas and Kasperbauer, Ann Otol Rhinol Laryngol. 2000;109:411-421.

Surgical Approaches and Recurrence Challenges

Surgical Approaches

- Complete excision or resection¹
- Partial resection or debulking²
- Staged surgery (helps protect function)²
- Combined approaches²
 - Surgery with sclerotherapy (reduces recurrence)

1/3

Surgical complications
occur in up to 1/3 of patients³⁻⁵,
including:

- Intraoperative blood loss in children
- Hemorrhage of cyst, bleeding, infection, and sinus thrombosis
- Head and neck LMs have increased risk of nerve damage

>50%

Recurrence rates^{4,6,7}
due to incomplete resection results

Increased mortality⁶

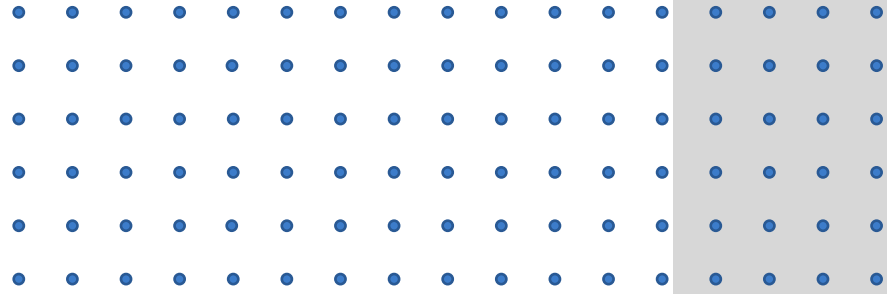
Post-surgical mortality increases
based on how extensive the cyst is and
in newborns⁸

¹Ma et al. Exp Ther Med. 2017;14(2):1293-1298; ²Lee et al. Semin Intervent Radiol. 2024;41(4):389-403; ³Emery et al. 1984; ⁴Giguère et al. 2002; ⁵Orvidas and Kasperbauer, 2000; ⁶Ha et al. 2014; ⁷Weitz-Tuoretmaa et al. 2014

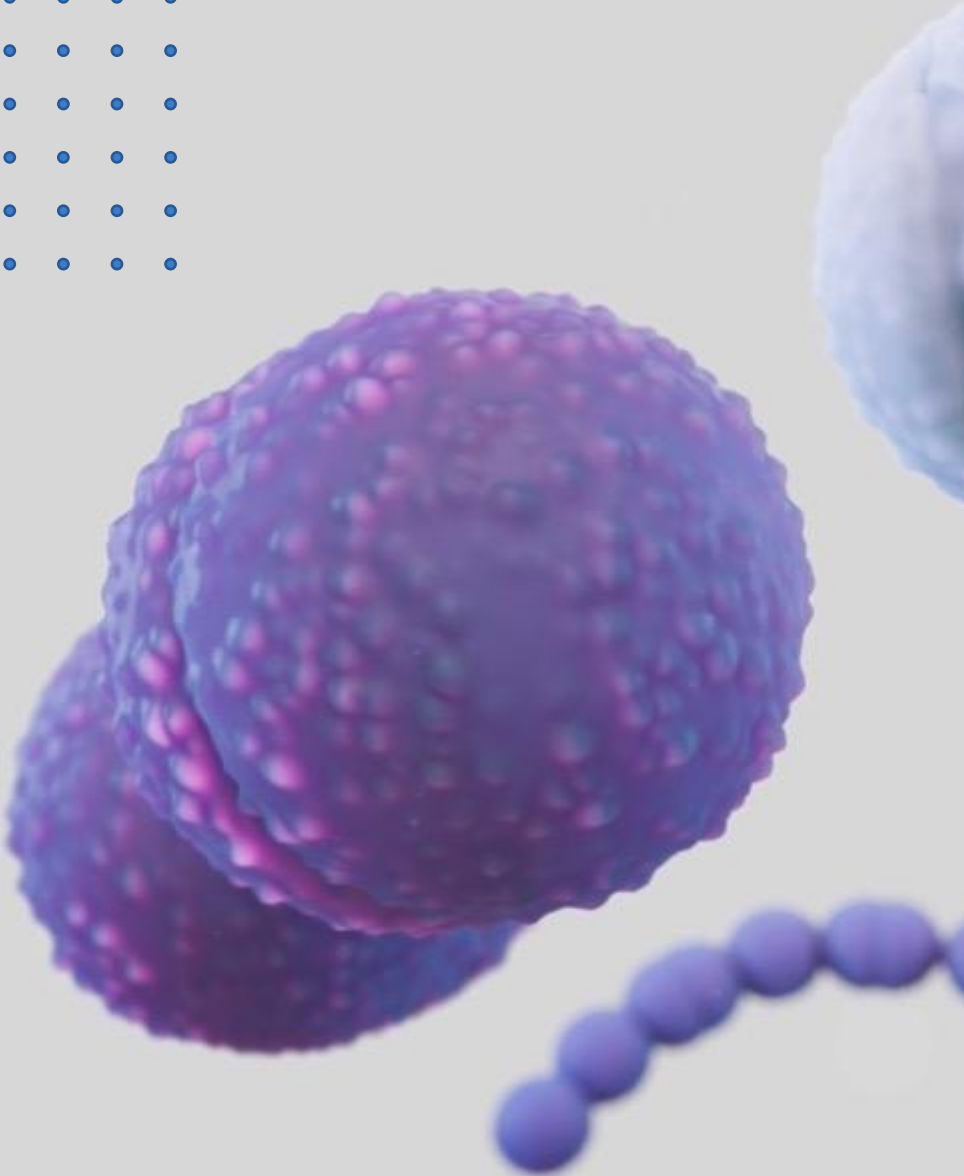
Significant Need for a More Targeted Approach to Treating LMs



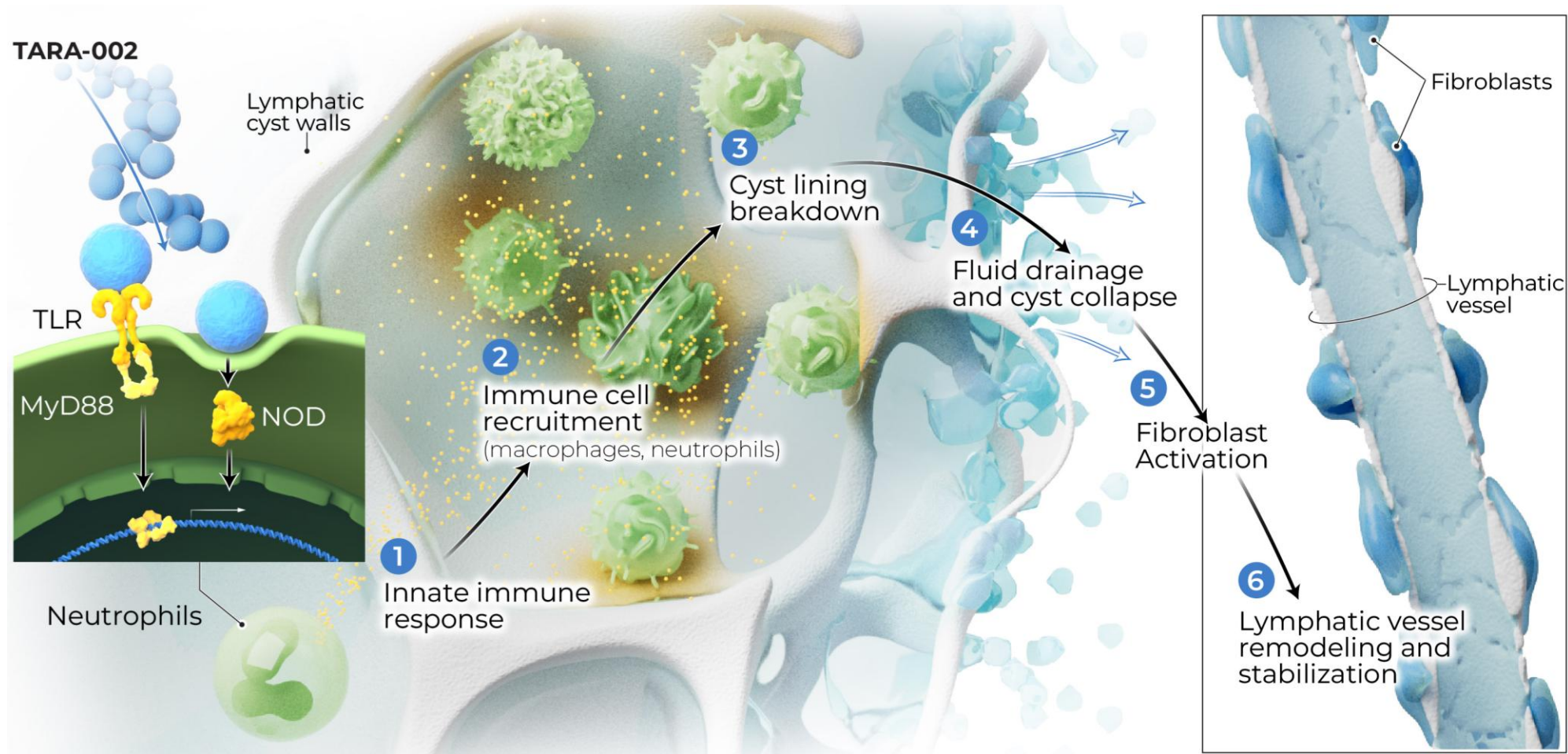
- **FDA-approved therapy** supported by clinical studies demonstrating efficacy and safety with standardized dosing regimen
- **Targeted therapy** vs. cytotoxic or chemical approach
- **Minimally invasive and well tolerated**
- **Minimal sedation** in an ambulatory setting **without hospitalization** or overnight stays
- **Resource efficient** process that can be performed in an ambulatory setting without general anesthesia



TARA-002



TARA-002: A Unique TLR2/NOD2 Agonist Derived From *Streptococcus pyogenes* That Brings the First Immunologic Mechanism to LMs



TARA-002 ignites both innate and adaptive immunity through dual TLR2/NOD2 activation, driving potent, local, cystic responses via fully inactivated bacteria^{1, 2, 3}

Pivotal Phase 2 STARBORN-1 Trial

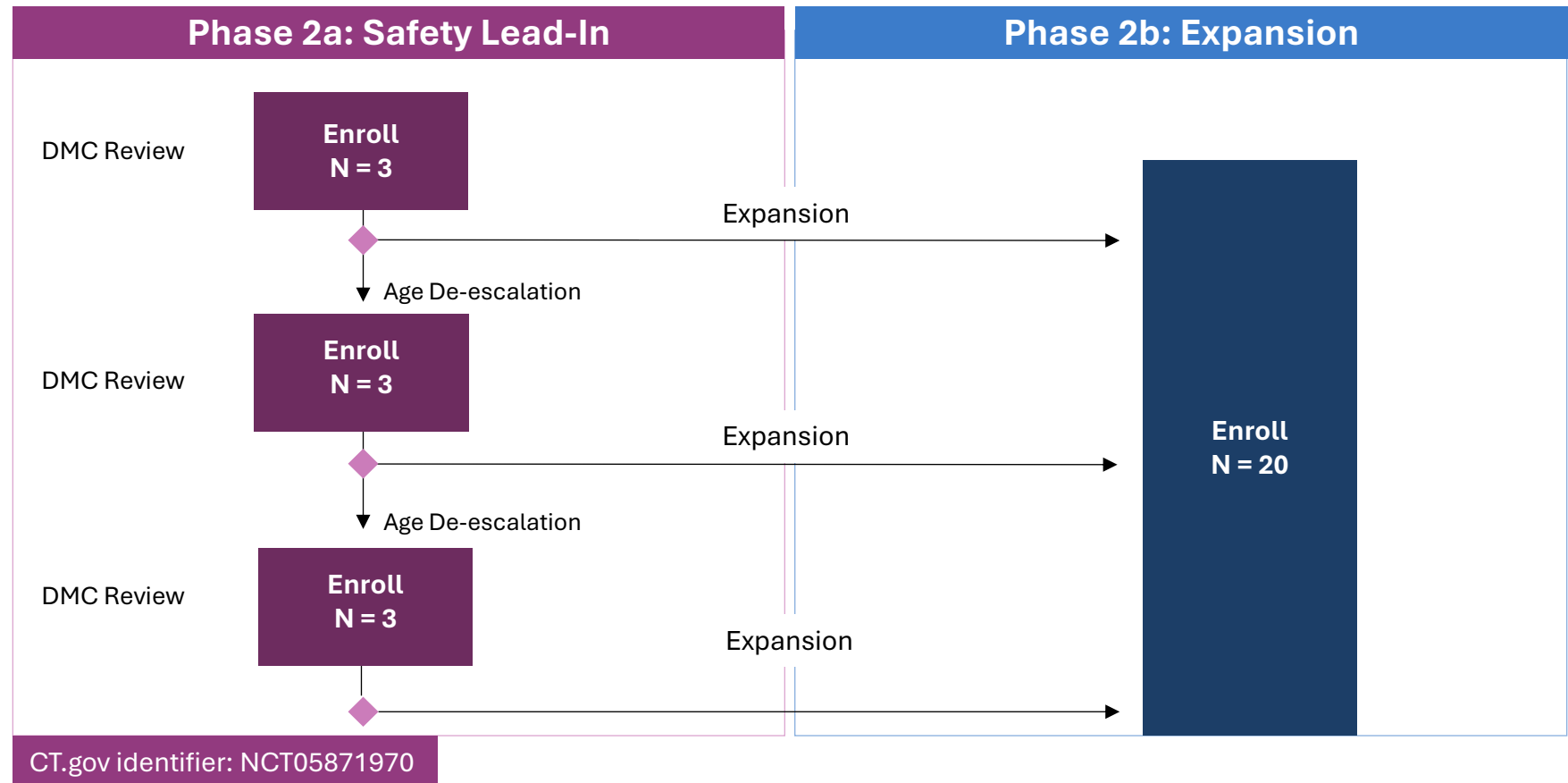
STARBORN-1 is a Single Arm, Open-Label Safety and Efficacy Study of TARA-002 in Pediatric Patients with Macrocytic & Mixed cystic LMs (N=29)

- Patients receive up to four injections of TARA-002 spaced approximately six weeks apart
- DMC review with FDA for each safety lead-in cohort before expansion and age de-escalation
- **Clinical Success is defined as patients who have either a complete response (90% - 100% reduction from baseline in total LM volume) or substantial response (60% - 90% reduction)**

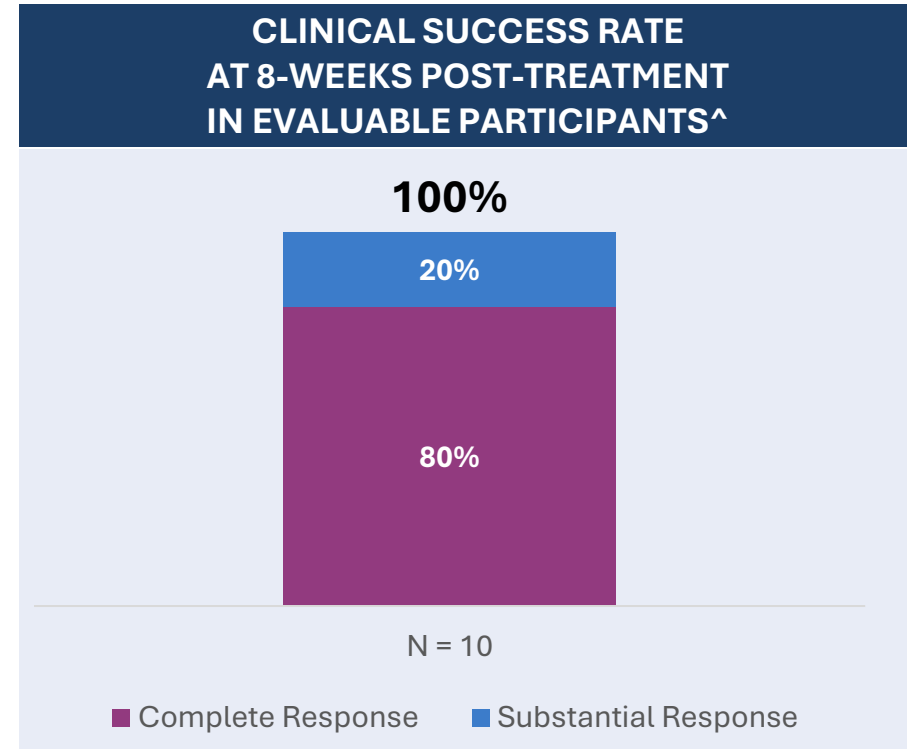
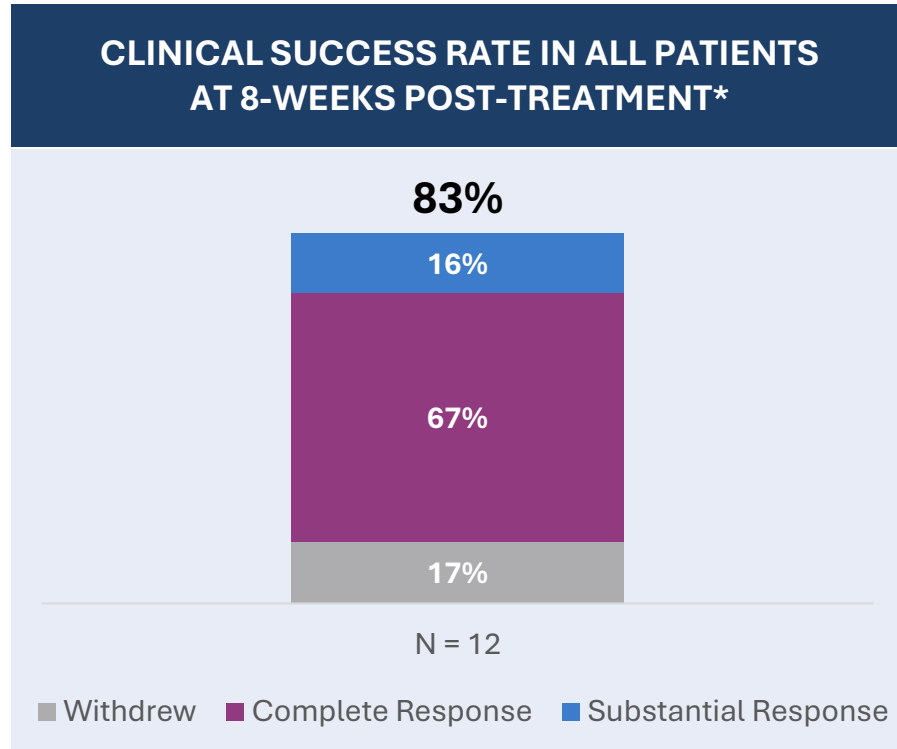
6 years to < 18 years

2 years to < 6 years

6 months to < 2 years



TARA-002 Demonstrated Clinical Success in 83% of Participants that Completed Treatment and 100% of Evaluable Participants



2 participants withdrew before 8-week post-treatment assessment

- 1 participant was mis-diagnosed and had a rare form of cancer and did not respond to treatment
- 1 participant dropped out after achieving a marked resolution of the LM: received 2 doses (160 ml aspiration at first dose reduced to 10 ml aspiration at second dose)

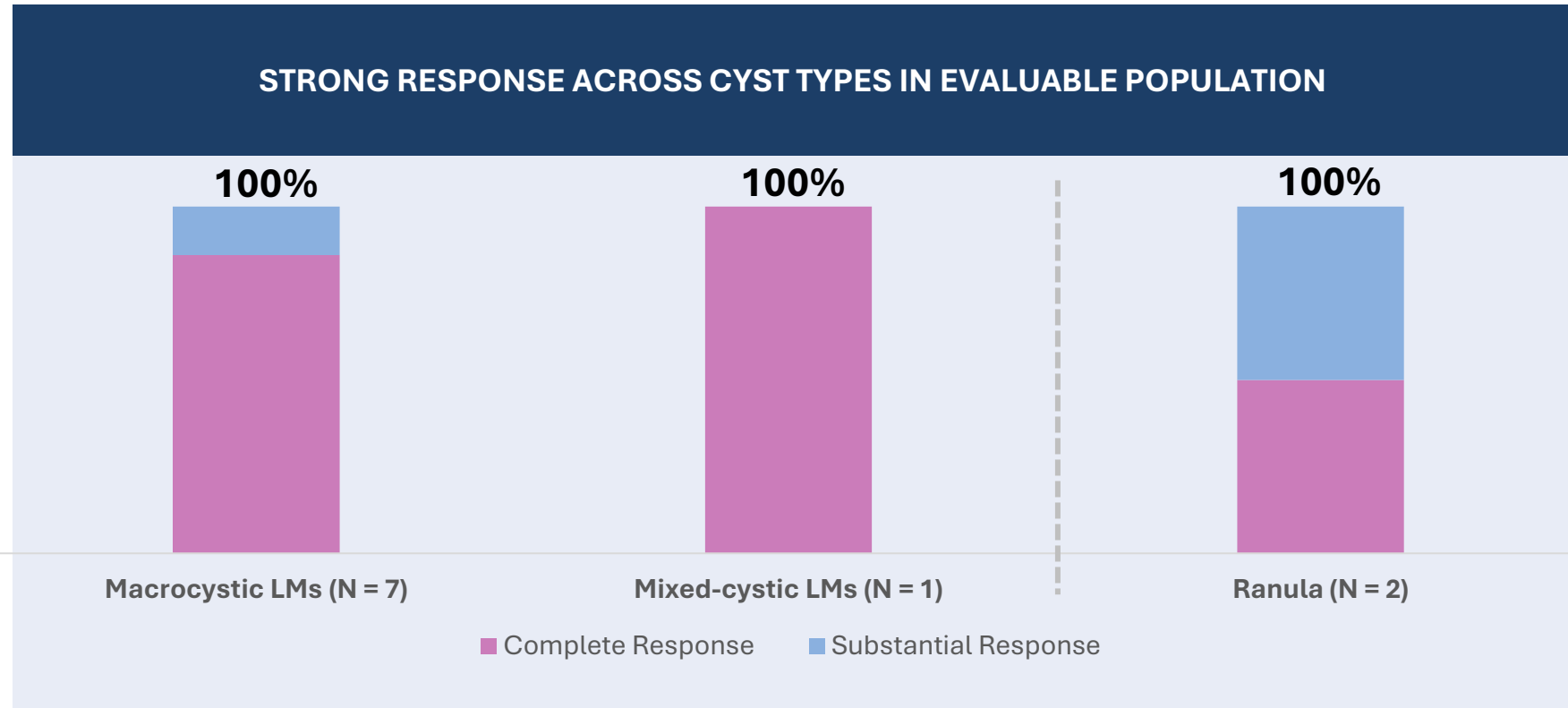
Response was assessed via central imaging (MRI or CT) or via Investigator assessment (physical exam, visual inspection and ultrasound). Clinical success is defined as complete (90-100% reduction) or substantial (60-90% reduction) response of the cyst from baseline in total LM volume.

Note: Response assessment includes all participants who have completed treatment; Excludes 3 participants who are still in treatment and one whose post-treatment assessment is pending

*Participants who received at least one intracystic injection of the study intervention.

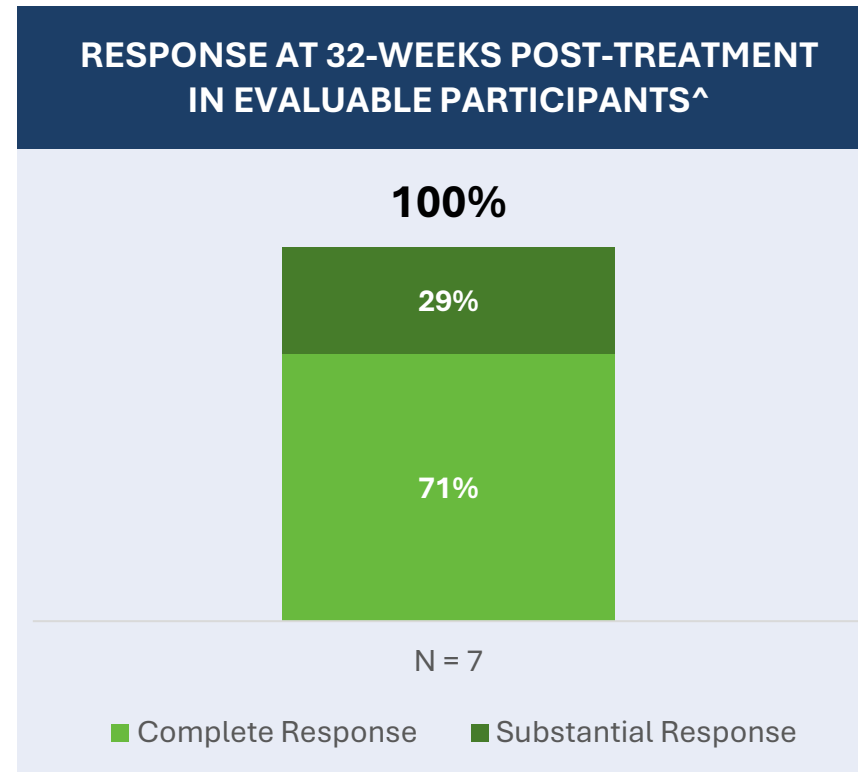
^Participants who completed the 8-week post-treatment assessment.

STARBORN-1 Interim Results: Evaluatable Participants Across Cyst Types



- Clinical success was achieved with one or two doses of TARA-002 in 80% of participants.
- One participant with a complete response and one participant with a substantial response were subsequently diagnosed with a ranula (a different type of maxillofacial cyst from LMs)

TARA-002 Demonstrated 100% Durable Response at 32-Weeks



- **7 participants** have reached the 32-weeks post-treatment assessment and remain disease free

[^]Excludes ongoing participants who had not yet reached the 32-weeks post-treatment assessment as of the data cut off, and one participant who had a complete response at the 8-week assessment but discontinued prior to 32-weeks post-treatment.

TARA-002 Has Demonstrated Meaningful Results in LMs Patients Treated in the STARBORN-1 Study

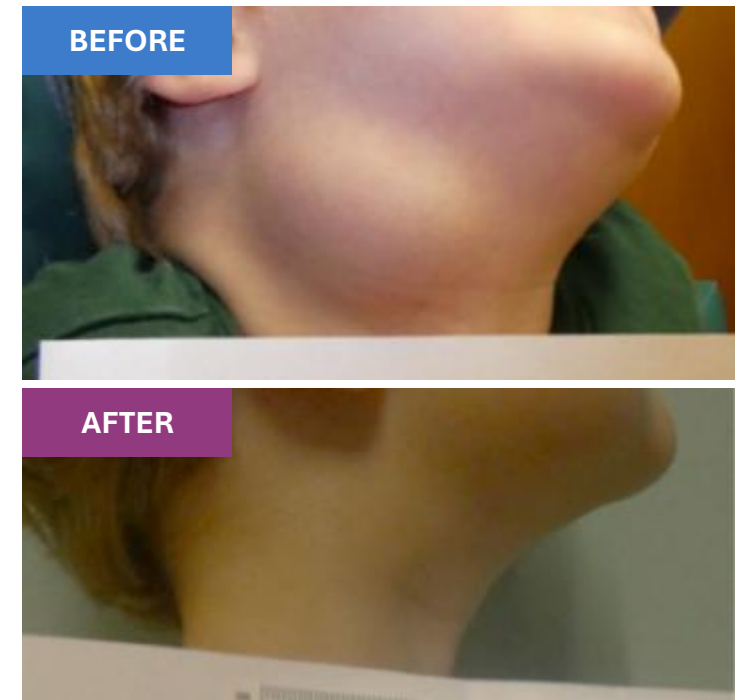
Medical photography: Baseline and 8-week post-treatment results for three participants treated with TARA-002 in the STARBORN-1 trial



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.



Baseline 28mL macrocystic LM received 2 injections of TARA-002 (20mL [1], 0.5mL [2]); 3 years of age.

TARA-002 Has a Favorable and Well-Tolerated Safety Profile

- Most AEs were mild to moderate
- No serious TEAEs or AESIs have occurred to date

Number of Participants, 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)
Related TEAEs >10%, n (%)					
Swelling	5 (31)	0 (0)	4 (25)	1 (6)	0 (0)
Fatigue	4 (25)	3 (19)	1 (6)	0 (0)	0 (0)
Erythema	2 (13)	2 (13)	0 (0)	0 (0)	0 (0)
Headache	2 (13)	2 (13)	0 (0)	0 (0)	0 (0)
Injection site pain	2 (13)	2 (13)	0 (0)	0 (0)	0 (0)
Injection site rash	2 (13)	2 (13)	0 (0)	0 (0)	0 (0)
Pyrexia	2 (13)	2 (13)	0 (0)	0 (0)	0 (0)
Irritability	2 (13)	1 (6)	1 (6)	0 (0)	0 (0)
Neck pain	2 (13)	1 (6)	1 (6)	0 (0)	0 (0)
Somnolence	2 (13)	1 (6)	1 (6)	0 (0)	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



KOL Discussion

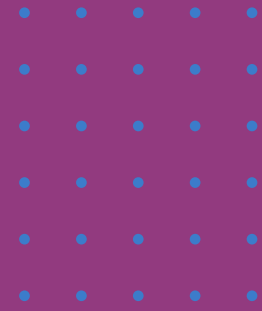
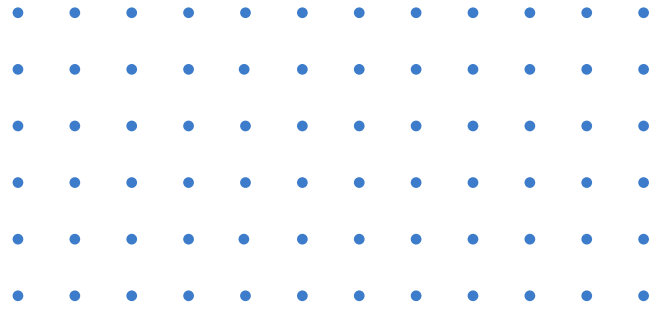
Jesse G.A. Jones, MD, University of Alabama –
Departments of Neurosurgery and Radiology

STARBORN-1 Results: Clinical Trial for Significant Unmet Need in LMs

- 100% of evaluable participants achieved clinical success
- TARA-002 demonstrated favorable safety and tolerability profile with no serious adverse events reported
- Clinical Success was achieved with one or two doses in 80% of participants
- TARA-002 has shown strong safety and efficacy results

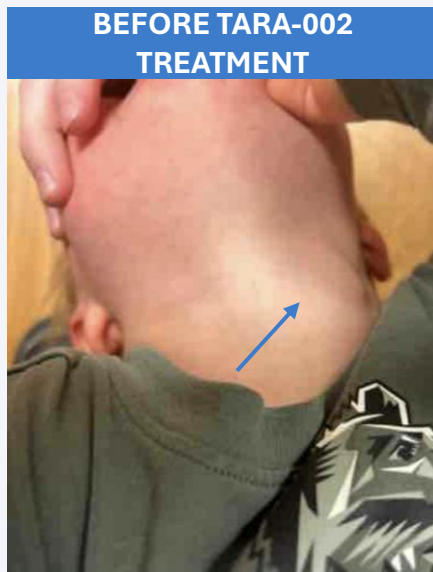
*NCT05871970

Note: Clinical Success is defined as the proportion of patients who have either a complete response (90% - 100% reduction from baseline in total LM volume) or substantial response (60% - 90% reduction)



Case Studies

Expanded Access Case Review: Patient with LM Overview



- 3-year-old male patient with a LM (+ cystic fibrosis) in the left anterior neck with recurrences
- Prior treatments received:
 - Sclerotherapy with 2 mL of 40 mg/cc doxycycline and 5 mL Sotradecol and Gelfoam without resolution
 - Sclerotherapy with 3.5 mL of Sotradecol mixed with iodinated contrast without resolution
 - Sclerotherapy with 5 mL of ethanol and contrast without resolution
- This patient has underlying cystic fibrosis, so the patient did not qualify for inclusion in STARBORN-1
- Expanded access of TARA-002 was granted

Expanded Access Case Review: Patient with LM – Results



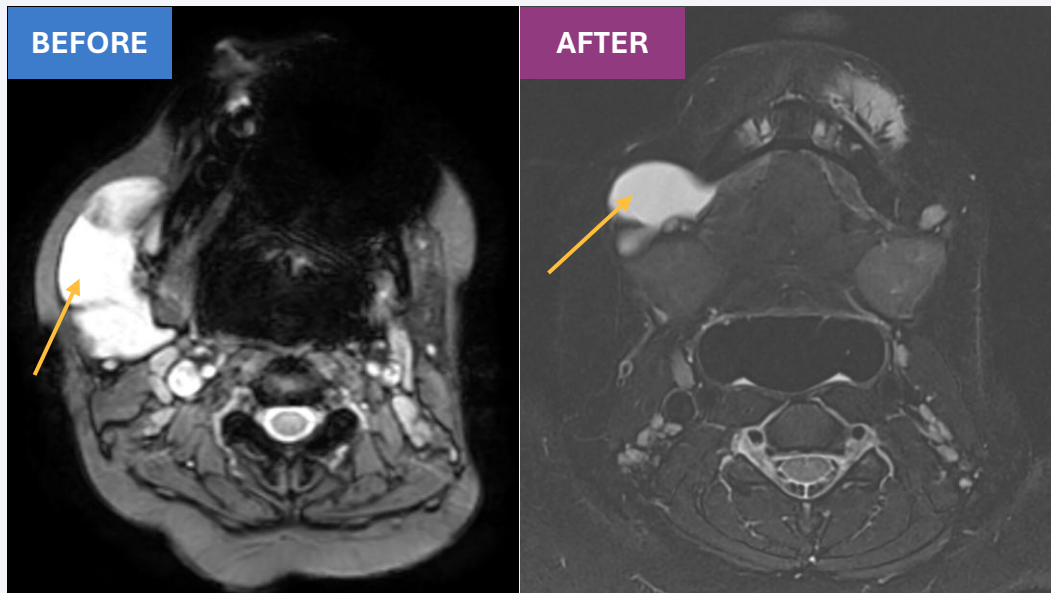
- Initial ultrasound showed an ovoid unilocular fluid collection measuring 1.8 x 1.2cm
- This patient received one injection of TARA-002 on 03-December-2025
 - The aspirated volume was 4 mL and the injected volume of TARA-002 was 4 mL
- The patient returned for a follow-up visit on 10-February-2026
 - Since the prior ultrasound, there was near resolution of the malformation in the left anterior neck.
 - Questionable residual 2.4 x 4.8 mm fluid collection anterior to the internal jugular vein
 - An additional injection of TARA-002 was not needed
- The assessment of response was substantial resolution based on visual inspection, physical examination, and ultrasound-based lesion size reduction
- No adverse events were reported

STARBORN-1 Case Review: Ranula – Overview

- 7-year-old female participant initially diagnosed with a macrocystic LM located infra and suprahyoid right (de Serres stage III), later diagnosed as a ranula
- Prior treatment included:
 - One dose of 5 mL doxycycline/10 mL sotradecol/10 mL ethanol with no resolution
 - One dose of 5 mL absolute ethanol/5 mL polidocanol with no resolution
- Baseline MRI measured 51.36 mL and the participant received 4 injections of TARA-002

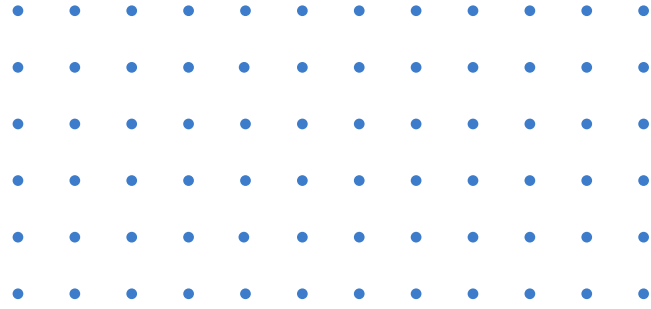
Volume	Aspirated (mL)	Injected (mL)
Dose #1	38	20
Dose #2	14	10
Dose #3	6	6
Dose #4	2.5	2

STARBORN-1 Case Review: Ranula – Results



Baseline 51mL macrocystic LM (later ranula) received 4 injections of TARA-002 (20mL [1], 10mL [2], 6mL [3], 2mL[4]); 7 years of age.

- The 8-week post-treatment MRI demonstrated a **substantial response** (78.8% reduction) and the investigator assessment of response was substantial resolution
 - The 32-week post-treatment visit is upcoming
- One possibly related TEAE of pain in jaw (Grade 1) started 1 day after the first injection and is recovering/resolving
- Solicited local reactions included pain, redness, and swelling
 - No difficulty breathing, facial paralysis, or stridor was reported for any injection
- Solicited systemic reactions included drowsiness, headache, nausea/vomiting, and fatigue
 - No chills, loss of appetite, fever, or rash were reported for any injection
- The diary was not completed for the fourth injection due to a technical error so no reactions were reported

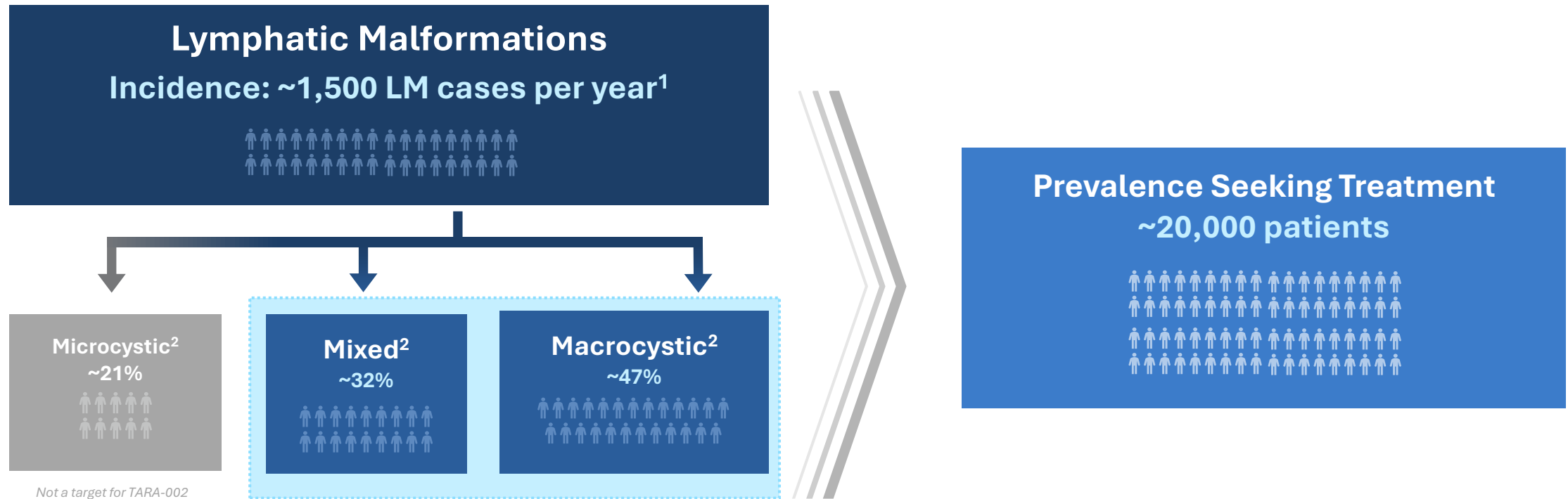


LMs Market Overview:

TARA-002 Has the Potential to Become the First and Only FDA Approved Treatment for Patients with Macrocystic LMs

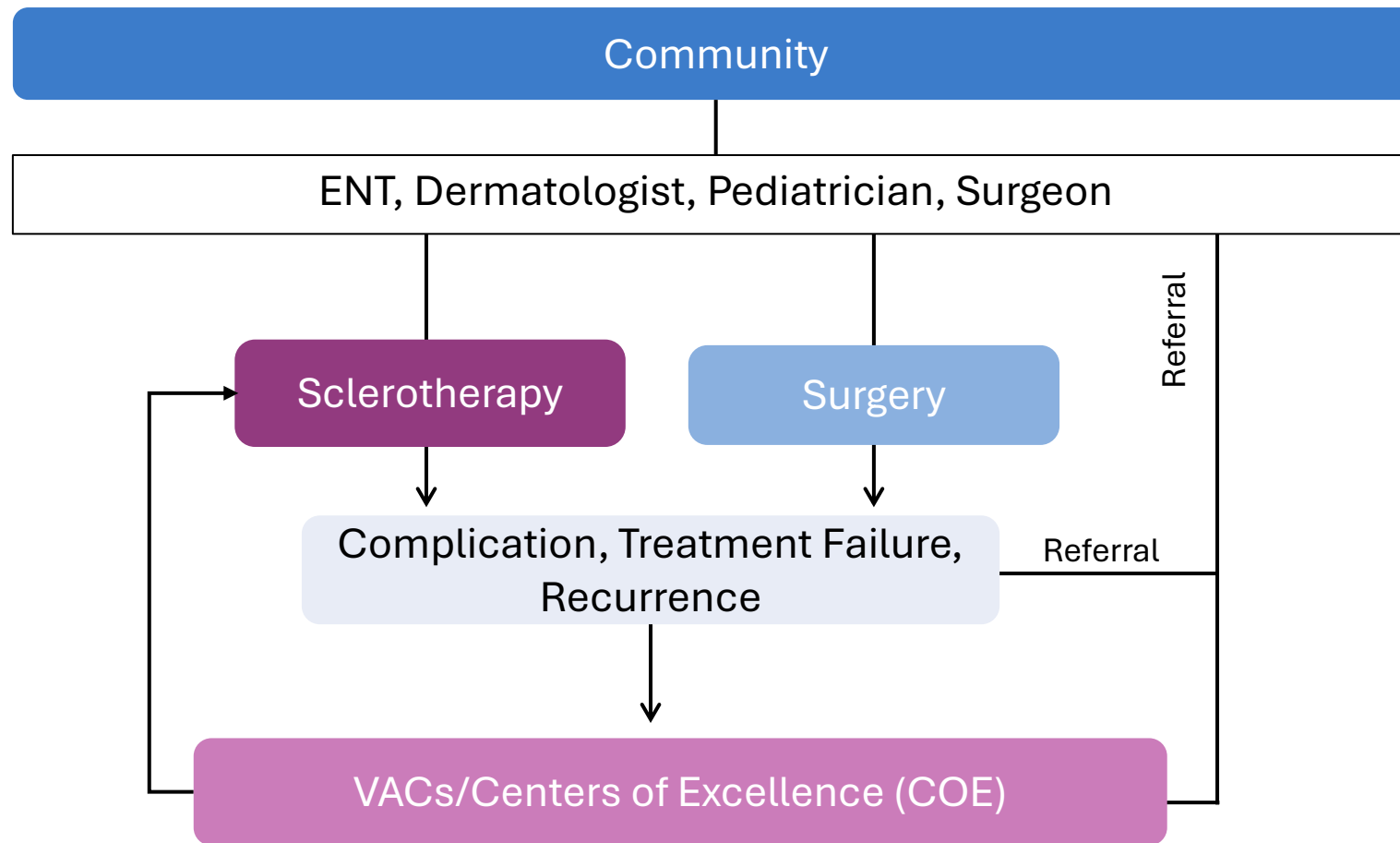


Attractive Market Opportunity in Macrocytic and Mixed Cystic LMs



Total addressable market estimated to be greater than \$1bn³

Patients are Typically Diagnosed in the Community Setting and Most are Referred to Vascular Anomaly Centers (VACs)



Real-World Findings from Qualitative Research Study

Highlight Clinical, Psychological and Structural Burden of LMs¹



Patient Perspectives

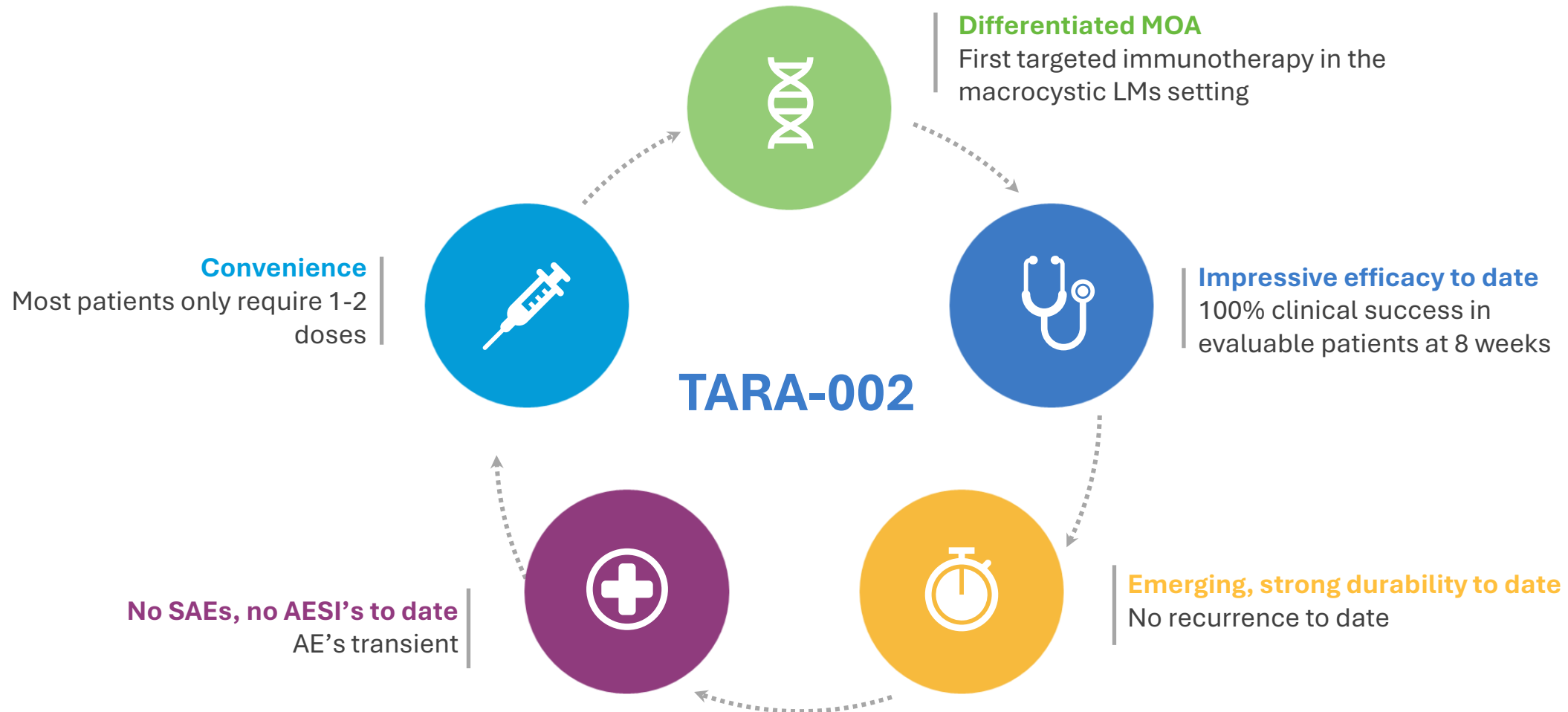
1. **Pain, fatigue and disability**
2. **Functional Issues**, including difficulties with mobility, sleep and concentration
3. **Medical anxiety** stemming from recurrent procedures and trauma
4. **Social isolation** following stigma and bullying linked to visible differences
5. **Financial burden** and strain from repeated interventions and travel
6. **Emotional burden**, with caregivers and patients alike reporting emotional exhaustion



Provider Perspectives

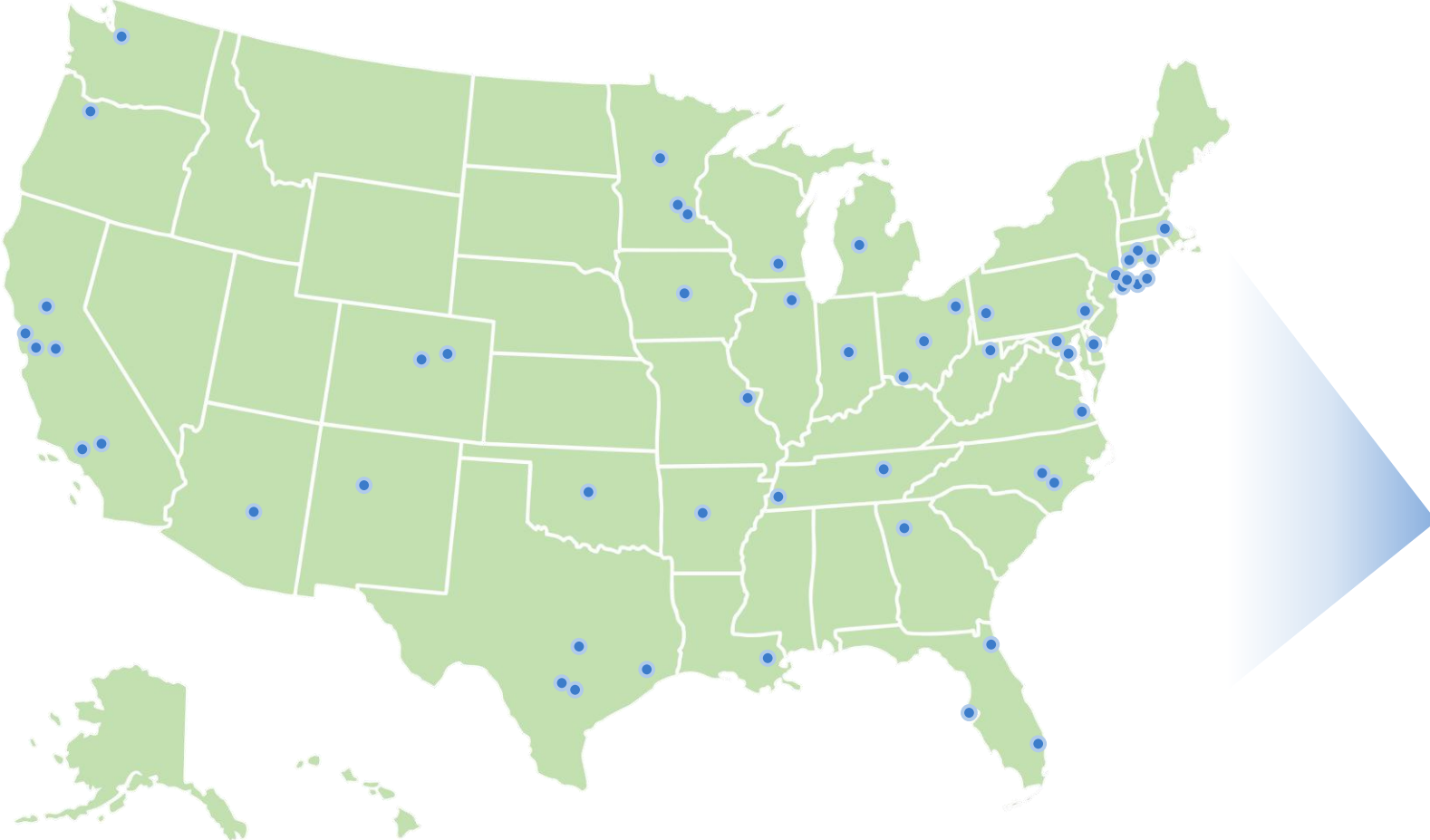
1. **No FDA approved treatments** for macrocystic LMs
2. **Increased patient burden** and recurrence with surgery
3. **No standardized dosing regimens** for existing sclerotherapy
4. **Variable safety risks** based upon provider preference and experience
5. **Increased recurrence rates** with other treatment options

TARA-002 Has Significant Potential Value for LMs Patients & Providers



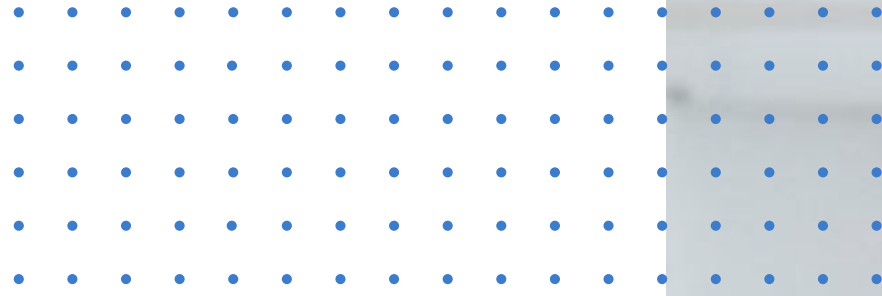
Orphan drug pricing opportunity based upon incidence, effectiveness and durability

The Top 100 Accounts for LMs Treated Patients Represent ~80% of the Total LM Treated Population



Account Rank	% Total LM Patients with Sclerotherapy Claims
Top 20	54%
Top 50	70%
Top 100	80%
Top 200	86%

TARA-002 can achieve a high target penetration with a focused commercial launch



Summary



OK-432 Demonstrated Clinical Efficacy in a Variety of Maxillofacial Cysts, Suggesting Significant Future Growth Opportunity for TARA-002

Congenital and acquired cystic masses of the craniofacial region



Ranula

Epidemiology: ~0.2 cases per 1,000 persons (~68k US)¹
of patients treated with OK-432: 23²
Treatment paradigm: Surgery / sclerosing agents
Unmet need: Surgery leads to high rates of recurrence



Thyroglossal Duct Cyst

Epidemiology: > 1 million³
of patients treated with OK-432: 17⁴
Treatment paradigm: Surgery
Unmet need: Surgery leads to high rates of recurrence

TARA-002 Provides a De-Risked Opportunity for a Significant Unmet Need



HIGH UNMET NEED AMONG PATIENTS

- No FDA-approved therapies
- Current off-label treatment options have significant gaps



DE-RISKED PROGRAM WITH SUPPORTIVE CLINICAL DATA

- TARA-002 predecessor compound OK-432 is approved in Japan and has been the standard of care for LMs for 30+ years
- TARA-002 clinical data showing the same strong results
- STARBORN-1 expected to be fully enrolled by the end of 2026



POTENTIAL FOR PRIORITY REVIEW VOUCHER UPON APPROVAL

- Granted Rare Pediatric Disease Designation (RPDD) in 2021
- Intent to submit BLA in 2H'27



POTENTIAL TO TREAT OTHER MAXILLOFACIAL CYSTS

- Historical literature and patient experience indicate that TARA-002 could have the potential to treat other maxillofacial cysts

Q&A



Thank you!

