PROTARA THERAPEUTICS

NEWSLETTER

Dear LM Community,



INTRODUCING PROTARA THERAPEUTICS

Hello! We're pleased to introduce ourselves to the Lymphatic Malformation (LM) community. Protara is a clinical-stage biotechnology company focused on developing meaningful therapies for people living with rare diseases and cancer. We are located in New York City and have about 50 employees dedicated to our mission.

Today, we're excited to share an update on our STARBORN-1 study, which is exploring TARA-002 as a potential therapy for pediatric patients with macrocystic and mixed cystic LMs. We're grateful for the continued collaboration and support of the LM community as we work to bring forward new treatment options.

ABOUT TARA-002

TARA-002 is designed to start an immune response that shrinks the LM cyst. TARA-002 is made from a type of bacteria that is no longer alive, so it cannot cause an infection. Even though the bacteria are no longer alive, they help "wake up" the body's immune response.

This response helps the immune system target the cyst by breaking down its lining and allowing the trapped fluid to drain. As the fluid drains, the LM may begin to shrink and, in some cases, collapse. TARA-002 also supports the growth of healthy tissue in the lymphatic vessel, which may help prevent the cyst from coming back.

TARA-002 was developed from the same master cell bank as OK-432 (Picibanil®), a therapy that has been approved in Japan for the treatment of LMs for over 30 years. TARA-002 remains investigational and is not yet approved by the FDA or any other regulatory agencies.



STARBORN-1 STUDY OVERVIEW

STARBORN-1 is a Phase 2, open-label study, which means that all participants receive TARA-002. The study is evaluating the safety and potential benefits of TARA-002 in participants 6 months to less than 18 years of age with macrocystic and mixed cystic LMs. Participants receive up to 4 injections of TARA-002 directly into the target LM, given as one injection every 6 weeks. The study is currently enrolling participants at multiple locations across the United States.

To learn more about the study and participating sites, please visit our STARBORN-1 study website or ClinicalTrials.gov: NCT05871970. For additional information about our program and TARA-002, you can watch our recent webinar featuring Dr. Nancy Bauman, Pediatric Otolaryngologist and Director of the Vascular Anomalies Clinic at Children's National

Hospital, and visit our corporate website. *PLEASE NOTE: The photos contained in the webinar and on the corporate website are examples of participants who received treatment in this trial. These results are not promised for all participants.*

RECENT NEWS ABOUT STARBORN-1 AND TARA-002

Protara recently reported meaningful progress in addressing the significant unmet need facing LM patients and their families.

In November 2025, we shared positive interim findings from the ongoing STARBORN-1 study. To date, 12 children have been treated. All who completed their eight-week follow-up showed improvement, with most experiencing a complete or near-complete reduction. Many participants responded after just one or two injections, with side effects mostly mild, and no serious safety concerns were reported.

In January 2026, Protara announced that the U.S. Food and Drug Administration (FDA) granted both Breakthrough Therapy and Fast Track designations to TARA-002. The FDA grants these designations to expedite drug development for potential treatments that the FDA sees as promising for diseases with serious unmet needs. We are working closely with the FDA to help advance TARA-002's development and review as quickly and carefully as possible.



LOOKING AHEAD

At Protara, we understand the urgent need for new, safe, and effective treatments for LMs. We're dedicated to moving TARA-002 forward and we're deeply grateful for the patients and families contributing to this important research. We will continue to provide updates on the STARBORN-1 program through our patient advocacy partners.

We invite you to read our press releases here and encourage you to reach out to your healthcare provider if you have questions about the STARBORN-1 study or TARA-002.

Thank you for your interest – we look forward to continuing to partner with the LM community!

The Protara Team