

Treatment with NeoCast, a Next-Generation Liquid Embolic, Results in Substantial Chronic Subdural Hematoma Resolution and Functional Outcome Gains in Final EMBO-02 First-in-Human Results

Late-Breaking Data Presented at the Society of Neurointerventional Surgery (SNIS) Annual Meeting

WALTHAM, Mass., July 22, 2026 — Arsenal Medical, a clinical-stage company developing innovative biomaterial-based devices, announced late-breaking results from the EMBO-02 clinical study. In EMBO-02, NeoCast™, a shear-responsive, solvent-free liquid embolic was evaluated for middle meningeal artery embolization (MMAe) to treat chronic subdural hematoma (cSDH).

Results presented today at the Society of Neurointerventional Surgery (SNIS) annual meeting in Seattle showed that the study met its primary feasibility and safety endpoints with positive clinical outcomes. At final follow-up, 96% (23/24) of participants achieved at least 50% volume resolution, and 75% (18/24) had complete hematoma resolution. Functional outcomes were strong, with 79% of patients improving over baseline on mRS and quality-of-life measures through 180 days. Notably, 79% (19/24) of patients were treated with embolization alone, and 10 subjects were treated without general anesthesia.

“These NeoCast results are encouraging in ways that could have meaningful implications for both physicians and patients,” said Tim Phillips, MBBS, GDSA, FRANZCR, interventional neuroradiologist at the Neuro-Intervention and Imaging Service of Western Australia (NIISwa), Sir Charles Gairdner Hospital in Perth, Western Australia, and an investigator in the EMBO-02 study. “In my experience, NeoCast demonstrated highly predictable distal penetration, allowing effective embolization without the need to advance the microcatheter deep into the target vasculature, which simplified and streamlined the procedure. Equally important, because NeoCast is free of toxic solvents, patients experienced a virtually pain-free injection. The ability to perform middle meningeal artery embolization without sedation represents a meaningful advancement in patient care.”

Arsenal Medical recently announced FDA Investigational Device Exemption (IDE) approval for RADIANT, a prospective, randomized, multicenter study for the treatment of symptomatic subacute and chronic subdural hematoma (cSDH) adjunctively with surgery. The trial will compare NeoCast to Onyx LES, an embolic agent that is FDA-approved for treatment of cSDH in conjunction with surgery.

“EMBO-02 has given us a strong foundation to take the next step with NeoCast. With RADIANT, we will now evaluate those insights in a rigorous, prospective, randomized, multicenter pivotal trial,” said David J. Fiorella, MD, PhD, neuroradiologist at Stony Brook University Hospital, the medical monitor of the EMBO-02 and RADIANT studies, who presented the late-breaking results. “There will be significant interest in next-generation

embolics that can reliably achieve the level of robust distal occlusion that NeoCast demonstrated in EMBO-02 as the field of neurointervention manages this patient population and evolves new care pathways.”

“The positive first-in-human results from EMBO-02 reflect the dedication of our team and the invaluable contributions of our clinical and scientific collaborators,” said Upma Sharma, Ph.D., president and CEO of Arsenal Medical. “We believe that the enthusiasm we have seen from physicians as we launch the pivotal RADIANT trial reflects significant unmet need for next-generation embolic solutions. We are energized by the momentum behind NeoCast and look forward to partnering with leading investigators to further evaluate its potential in the RADIANT pivotal study.”

About NeoCast™

NeoCast is a next-generation, solvent-free, non-adhesive liquid embolic, which is engineered to reach distal microvasculature without causing pain. NeoCast’s shear-thinning properties enable it to reach small vessels and to occlude blood flow to tumors and diseased tissues. NeoCast is formulated for precise, controlled delivery without the harsh solvents or adhesives associated with many embolics. NeoCast demonstrated feasibility in two first-in-human studies: (1) in preoperative embolization of hypervascular brain tumors in the EMBO-01 and (2) in MMA embolization for cSDH in EMBO-02.

About the EMBO-02 Study

The EMBO-02 study (ACTRN12624000659505) is an open-label, multicenter, prospective, externally monitored, core lab adjudicated, feasibility clinical trial. The primary safety endpoint is device-related disabling stroke or neurological death within 30 days of embolization. The primary feasibility endpoint is the successful injection of NeoCast, resulting in complete occlusion at, or distal to, the point of injection.

Arsenal Medical

Arsenal Medical is a privately held, venture-backed, clinical-stage company developing innovative biomaterials to address challenging and underserved medical problems. Its lead products target neurovascular and trauma conditions. The company was founded by academic luminaries Robert Langer and George Whitesides, together with entrepreneur-investor Carmichael Roberts, who shared a vision for how materials can transform medical devices. Learn more at www.arsenalmedical.com.

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