

# Arsenal Medical Announces Complete Enrollment of the Initial Cohort in the EMBO-02 Study Assessing NeoCast<sup>™</sup> for the Treatment of Chronic Subdural Hematoma

WALTHAM, MA - February 6, 2025 – Arsenal Medical, a clinical-stage company developing medical devices from innovative biomaterials, today announced the complete enrollment of an initial cohort of 10 patients in the EMBO-02 clinical study of NeoCast<sup>™</sup> to treat chronic subdural hematomas (cSDH) across three sites in Australia. NeoCast is a next-generation, non-adhesive, solvent-free, liquid embolic material designed for deep distal penetration.

EMBO-02 is an open-label, multi-center, prospective clinical trial to evaluate the early safety and feasibility of NeoCast to embolize target vessels of the subject's middle meningeal artery (MMA) to treat cSDH. Presentation of the initial cohort took place at the International Stroke Conference (ISC) on Wednesday, February 5<sup>th</sup>, via a late-breaking presentation by Dr. Laetitia de Villiers, Specialist Interventional and Diagnostic Neuroradiologist at Gold Coast University Hospital, Australia.

All MMA embolization (MMAe) procedures in the trial were successfully completed with NeoCast, and all patients passed the 30-day safety endpoint with no device-related serious adverse events. On average, investigators were "very satisfied" with NeoCast's acute performance and usability, highlighting the material's ease of use.

"NeoCast is a promising new material for treating cSDH," said Dr. Tim Phillips, lead Interventional Neuroradiologist at the Neuro-Intervention and Imaging Service of Western Australia (NIISwa). "NeoCast has differentiated performance characteristics. It is a uniquely responsive liquid embolic agent, and its physical properties allow continuous control and visualization throughout the injection. The ability to penetrate the microvasculature with the material is very impressive, as are our early clinical and imaging results. I'm excited about the potential of NeoCast to address the limitations of currently available liquid embolics."

"We are thrilled to announce the completion of enrollment of the initial cohort of EMBO-02," said Upma Sharma, CEO of Arsenal Medical. "Our ability to quickly enroll highlights the growing need for interventions to manage chronic subdural hematomas. This marks another significant milestone in our mission to develop NeoCast as a new material for embolization. This achievement would not have been possible without the dedication of the entire Arsenal team, our investigators and advisors, and the subjects who have been instrumental in advancing this promising therapy. We eagerly anticipate sharing the final results from EMBO-02 later as we progress toward larger studies."

To learn more about EMBO-02 and NeoCast visit arsenalmedical.com.

# About Chronic Subdural Hematoma (cSDH)

cSDH is the persistent bleeding of an injured vessel in the membrane that protects the brain (dura). It is typically caused by a fall or injury to the head (including minor head trauma) and can result in significant physical and cognitive decline. It is the most common neurosurgical condition in those 65 and older and has been categorized as a sentinel health event in the elderly<sup>1</sup>. Middle meningeal artery (MMA) embolization is an emerging minimally invasive procedure to treat and prevent the recurrence of cSDH by using an embolic agent to occlude the MMA.



# About NeoCast™

NeoCast<sup>™</sup> is a next-generation, solvent-free, non-adhesive liquid embolic material designed to preferentially reach distal microvasculature. It provides a complete cast of the vessel, achieving robust occlusion to stop unwanted blood flow. Developed with funding from the National Cancer Institute, NeoCast leverages shear-thinning science to reach the smallest vessels and halt blood flow to tumors and injured or diseased tissues. Its unique material characteristics deliver enhanced control during injection while eliminating harsh solvents and adhesive glues often found in current liquid embolic products. NeoCast addresses the limitations of existing embolic products for deep penetration into the microvasculature, offering easy deployment and consistent performance.

NeoCast, a clinical-stage product, demonstrated safety and feasibility in EMBO-01, a first-inhuman study evaluating its use in the preoperative embolization of hypervascular brain tumors.

# About Arsenal Medical

Arsenal Medical is a clinical-stage company that creates innovative biomaterials to solve 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, along with serial entrepreneur-investor Carmichael Roberts, who shared a vision for how materials can transform medical devices. <u>www.arsenalmedical.com</u>

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#### **References:**

1. Rai AT, Halak AA, Lakhani DA, et al Population-based estimates suggest middle meningeal artery embolization for subdural hematomas could significantly expand the scope of neurovascular therapies Journal of NeuroInterventional Surgery Published Online First: 11 April 2024. doi: 10.1136/jnis-2024-021686