

Arsenal Medical Announces Late-Breaking Results from First-in-Human Clinical Trial of NeoCast™ at the Society of Neurointerventional Surgery Annual Meeting

Data show NeoCast, a next-generation, solvent-free, non-adhesive liquid embolic, met primary endpoints and enabled significant distal penetration of hypervascular brain tumors

Additional preclinical data presented demonstrate NeoCast occluded approximately five times more vessel branches compared to the market-leading liquid embolic agent in swine kidneys

WALTHAM, MA – (July 24, 2024) – Arsenal Medical, a clinical-stage company developing medical devices from innovative biomaterials across the therapeutic spectrum, today announced that NeoCast™, a first-of-its-kind, shear-responsive liquid embolic material designed for deep distal penetration, met its primary feasibility and safety endpoints in the open-label, multi-center, prospective, EMBO-01 clinical trial.

“NeoCast has the potential to be a game-changer for liquid embolics,” said Lee-Anne Slater, MBBS MMed FRANZCR, Interventional Neuroradiologist at Monash Health and the principal investigator for the EMBO-01 trial. “The product was easy to handle and performed consistently and reproducibly during injection while providing excellent visibility during and post-procedure, unlike currently available options. Early results show that NeoCast has the potential to fill a treatment gap with a tool that’s straightforward for clinicians to use and will ultimately benefit patients; I am encouraged by its possibilities in other middle meningeal artery indications.”

NeoCast stands alone in clinically demonstrating predictable and well-controlled vascular occlusion. The late-breaking data presented today are further bolstered by an additional presentation highlighting preclinical study results showing that it occluded approximately five times more vessel branches with improved radiopacity compared to the market-leading liquid embolic in swine kidneys.

“These emerging preclinical and clinical data are exciting as they clearly demonstrate the potential for NeoCast to be an optimal liquid embolic agent for the treatment of neurovascular conditions that require distal penetration of the targeted vasculature,” said David Fiorella, M.D., Ph.D., Interventional Neuroradiologist and EMBO-01 medical monitor from Stony Brook University Medical Center. “Middle meningeal artery embolization for the treatment of chronic subdural hematoma is the application that immediately comes to mind. The existing clinical data have suggested that distal penetration into the meningeal circulation is associated with faster and more complete cSDH resolution. Moreover, this agent has the additional advantage of not incorporating an inflammatory solvent or inducing a thermal reaction upon polymerization. This characteristic should allow NeoCast embolization procedures to be carried out under conscious sedation rather than general anesthesia in many or most patients as we would expect that the agent would not create any pain or discomfort during the infusion.”

“This is an important milestone in the clinical development of NeoCast as a differentiated solution for middle meningeal artery embolization and other conditions where deep distal penetration is beneficial,” said Upma Sharma, Ph.D., CEO and President of Arsenal Medical. “NeoCast is making the leap from legacy products that utilize technology developed decades ago. We appreciate Dr. Slater and our other clinical investigators; their commitment and hard work have been crucial to this first experience.”

About EMBO-01

EMBO-01 enrolled five subjects with extra-axial tumors, from 5.0 +/- 1.2 cm in size and supplied by one or more branches of the middle meningeal artery.

Key Results

- The primary safety endpoint, freedom from device-related disabling stroke or neurological death within 30 days of the embolization, was met.
- The primary feasibility endpoint, successful injection of NeoCast into the targeted vessel(s) supplying the tumor prior to surgical resection resulting in complete occlusion of the targeted vessel(s) at or distal to the point of embolysate injection, was met.
- The study found that treatment with NeoCast resulted in tumor devascularization of 88% (standard deviation +/- 7%).
- Complete tumor resection was achieved in all five subjects, as graded by the surgeon.

About NeoCast™

NeoCast™ is a next-generation, solvent-free, non-adhesive liquid embolic material designed to preferentially reach distal microvasculature. Doing so 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, 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.

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. www.arsenalmedical.com

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Media Contact:

Jenna Kane
jennakane@healthandcommerce.com
480.388.9587