Arsenal Medical Receives FDA IDE Approval for the RADIANT Pivotal Trial of NeoCast™ in Chronic Subdural Hematoma

A randomized, controlled study of a novel liquid embolic, NeoCast, adjunctive to surgery

WALTHAM, Mass. – May 21, 2026 Arsenal Medical, a clinical-stage company developing innovative biomaterial-based devices, announced that the U.S. Food and Drug Administration (FDA) has granted Investigational Device Exemption (IDE) approval for RADIANT, a pivotal trial evaluating NeoCast™. NeoCast is a novel liquid embolic under development that is designed to achieve pain-free, predictable distal penetration of the middle meningeal artery (MMA).

RADIANT is 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 FDA-approved embolic agent. This will be the first FDA-approved head-to-head study of two liquid embolic agents for cSDH. Approximately 360 subjects will be enrolled in a 2:1 randomization across up to 35 sites in the United States and Australia.

“Chronic subdural hematoma is becoming one of the most common conditions we manage in neurointervention,” said Charles Matouk, MD, Neurosurgeon at Yale New Haven Hospital and co-principal investigator of the RADIANT trial. “RADIANT will evaluate NeoCast as a potentially differentiated liquid embolic designed to provide predictable distal penetration while minimizing patient discomfort.”

“FDA approval of our IDE is a major step in our effort to demonstrate that NeoCast can offer an innovative embolic to neurointerventionalists,” said Upma Sharma, PhD, CEO of Arsenal Medical. “As MMA embolization gains momentum, many physicians still rely upon legacy materials that can be difficult to use and that contain adhesives or harsh solvents. NeoCast is designed to be simple to use and well tolerated by patients. We are excited to get the RADIANT Trial underway.”

About NeoCast™

NeoCast™ is a novel, solvent-free, non-adhesive liquid embolic biomaterial 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. Complete EMBO-02 results will be released later this year.

About 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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