Serenity Medical's River Stent™ Demonstrates Sustained 4- to 5-Year Benefits in Patients with Idiopathic Intracranial Hypertension (IIH), Presented at SNIS Annual Meeting in Late-Breaking Session

Long-term data reinforce durability of venous sinus stenting as an evidence-backed, FDA-approved treatment option

Maple Grove, MN, July 22, 2026 (Globe Newswire) – Serenity Medical, a NeuroTechnology Investors (NTI) portfolio company and pioneer in venous sinus stenosis treatment, today announced during a late-breaking session of the Society of Neurointerventional Surgery (SNIS) 23rd Annual Meeting four- to five-year results of the River Study, the first multicenter evaluation of the novel venous sinus River stent™ for the treatment of Idiopathic Intracranial Hypertension (IIH), a serious neurological condition caused by elevated intracranial pressure that leads to debilitating chronic headaches, vision loss, and cognitive impairment. This long-term follow-up demonstrated durable clinical, radiological, and patient-reported benefits following River stenting, with sustained improvements across symptoms including headaches, vision, quality of life, and imaging outcomes.

"This is the long-term evidence physicians treating IIH wanted to know. The River stent's purpose-built design for the venous sinuses, combined with benefits demonstrated early and held over time, sets a new benchmark for treatment of this disease," said Adnan Siddiqui, MD, PhD, FAANS, FACS, FAHA, Vice Chairman and Professor of Neurosurgery, Jacobs School of Medicine & Biomedical Sciences, and an investigator in the River Study.

Clinical improvements observed at one year remained stable or continued to improve through long-term follow-up with no evidence of in-stent stenosis or thrombosis. Importantly, the clinical benefit of River stenting was observed regardless of weight loss. Key findings include improvements in:

- Headache relief: Sustained improvement in headache burden. No rebound or worsening headaches, and 90% achieved clinically meaningful improvement by year five
- Papilledema (swelling of the optic nerve) resolution: Papilledema resolved in 95.7% of participants by year two, and in 100% by years four and five
- Quality of life: Significant improvements were sustained through five years, with no evidence of long-term deterioration

"Four to five years out, we've seen durable improvements in headache burden, vision-related outcomes, and quality of life. That gives physicians confidence that venous sinus stenting with the River stent can change the trajectory for appropriate IIH patients," said Y. Pierre Gobin, MD, Founder of Serenity Medical and an internationally recognized neurointerventional expert practicing at Weill-Cornell Medicine in New York, NY.

IIH disproportionately affects overweight women aged 20–50, a demographic whose prevalence is increasing. For certain patients with severe IIH symptoms, finding appropriate surgical therapies that are FDA-approved and indicated to safely relieve their symptoms has been challenging. In March 2026, the FDA granted Humanitarian Device Exemption (HDE) approval – the first FDA approval of a cerebral venous sinus stent – to the River stent, which is specifically developed and purpose-engineered to treat severe, refractory IIH in adult patients who have failed medical therapy.

Serenity Medical has formed a strategic partnership with Radical Catheter Technologies to commercialize the River stent. The team is now expanding its collaborative reach across the NTI portfolio and beyond, serving as a commercialization partner — uniting its industry-leading neurovascular access and delivery catheters with other innovative neuro solutions to accelerate market adoption and broaden patient access to transformative care.

Humanitarian Device Exemption

The FDA has approved the humanitarian use of the River stent for adult patients with IIH with significant stenosis who are resistant or intolerant to medications. It is reserved for patients with severe headaches who have failed to respond to 6 months of medical therapy, including attempts at weight loss, or for patients who have had visual symptoms or visual signs that are vision-threatening despite medical therapy.

About Serenity Medical
Serenity Medical is a pioneering neurovascular device company dedicated to the treatment of venous diseases. Its flagship River Stent™ System, now FDA HDE-approved for severe, refractory IIH, is a purpose-engineered venous stent uniquely designed for the anatomy of the stenotic venous sinuses, featuring variable radial force and diameter, flexible construction, and reduced metal surface area to minimize thrombotic risk. Along with the Serenity Shepherd Stent™ System, which received FDA Breakthrough Device Designation for the treatment of severe pulsatile tinnitus in June 2026, the Company is expanding its portfolio of complementary technologies to optimize venous sinus stenosis procedures.

About the Radical Technologies Commercialization Team
Radical Technologies fields a specialized neurovascular team with deep expertise in bringing breakthrough medical technologies to market. Through hospital and KOL engagement, physician education, and ongoing clinical support, Radical ensures safe and efficacious adoption on a large scale. By integrating its industry-leading neurovascular access and delivery catheters with NeuroTechnology Investors' expanding portfolio of innovative neurovascular and neurosurgical solutions, Radical Technologies is building a unified commercial infrastructure to address significant unmet clinical needs and expand patient access to transformative care.

About NeuroTechnology Investors (NTI)
NeuroTechnology Investors (NTI) is a leading investment group dedicated to advancing breakthrough neurological technologies in the medical device sector, with a diverse portfolio that includes Synchron, Radical Technologies, Borvo Medical, and Serenity Medical. Established in 2016 and headquartered in Mountain View, California, NTI investors bring extensive clinical expertise to accelerate portfolio company development and improve patient access to transformative clinical solutions.

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