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NEWS RELEASE

Johnson & Johnson Receives FDA Approval for TRUFILL n-BCA Liquid Embolic System for the Treatment of Symptomatic Chronic Subdural Hematoma

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- TRUFILL n-BCA is now indicated for embolization of the middle meningeal artery (MMA) for the treatment of symptomatic subacute and Chronic Subdural Hematoma (cSDH) as an adjunct to surgery.
- Approval builds on a trusted solution in neurovascular embolization for over 25 years.

IRVINE, Calif., Dec. 18, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) – Today, Johnson & Johnson MedTech, a leader in neurovascular care, announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for the TRUFILL n-BCA Liquid Embolic System for embolization of the middle meningeal artery (MMA) for the treatment of symptomatic subacute and chronic Subdural Hematoma (cSDH) as an adjunct to surgery.

cSDH is often caused by minor head trauma that leads to bleeding between the dura and arachnoid membranes, particularly among older adults and those on anticoagulation therapy. While surgical intervention is the traditional standard of care, recurrence rate estimates range between 10% to 20%. Embolization of the MMA offers a minimally invasive endovascular approach by targeting smaller brain vessels thought to contribute to hematoma persistence and regrowth.[1]

The approval is supported by findings from the MEMBRANE randomized controlled trial, which evaluated the safety and effectiveness of MMA embolization in patients with cSDH[2]. The results of the MEMBRANE study demonstrated that TRUFILL n-BCA is superior in effectiveness compared to Standard of Care (SOC) for embolization in the MMA for the treatment of symptomatic cSDH[i], and importantly, TRUFILL n-BCA was demonstrated to be safe for treating

cSDH[2].

"This approval reinforces the enduring value of TRUFILL n-BCA and our commitment to delivering innovative technologies that improve outcomes for patients and address complex neurovascular conditions," said Christian Cuzick, President, Worldwide Neurovascular, Johnson & Johnson MedTech.

"There is an unmet need for new treatment options for chronic subdural hematoma, particularly for patients at risk of recurrence or complications from surgery," said Dr. Chris Kellner[ii], Director of Cerebrovascular & Intercerebral Hemorrhage programs, Mount Sinai, and investigator in the MEMBRANE trial. "The MEMBRANE study demonstrated a positive treatment effect in favor of TRUFILL over standard of care and reinforces the potential of MMA embolization to improve outcomes for patients with cSDH."

TRUFILL n-BCA has been a trusted solution in neurovascular embolization for over 25 years, supporting the treatment of patients with arteriovenous malformations (AVMs) since its original FDA approval in 2000. This expanded indication brings TRUFILL n-BCA's established performance into the treatment of cSDH, a condition where traditional surgical interventions may not always be suitable or effective for long-term control.

Cardiovascular Solutions from Johnson & Johnson MedTech

Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. Through a cardiovascular portfolio that provides healthcare professionals with advanced mapping and navigation, miniaturized tech, and precise ablation we are addressing conditions with significant unmet needs such as heart failure, coronary artery disease, stroke, and atrial fibrillation. We are the global leaders in heart recovery, circulatory restoration and the treatment of heart rhythm disorders, as well as an emerging leader in neurovascular care, committed to taking on two of the leading causes of death worldwide in heart failure and stroke. For more information, visit **https://www.jnjmedtech.com/en-US/companies/cerenovus** and connect on **LinkedIn**.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopedics, surgery and vision solutions at **https://thenext.jnjmedtech.com**. Follow us at **@JNJMedTech** and on **LinkedIn**. DePuy Synthes Sales, Inc. d/b/a CERENOVUS and Medical Device Business Services, Inc. are part of Johnson & Johnson MedTech.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to TRUFILL™ n-BCA. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at **www.sec.gov**, **www.jnj.com**, **www.investor.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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[i] As assessed in MEMBRANE study by the primary effectiveness endpoint of residual or re-accumulation of the cSDH (>10 mm) at 6 months (by an Independent Core Laboratory) or re-operation or surgical procedure on the cSDH within 6 months - OR 0.475 (95% CI 0.239 - 0.944) in Surgical cohort.

[ii] Dr. Chris Kellner serves as a consultant for Johnson & Johnson but was not compensated for this announcement

[1] Nouri A, Gondar R, Schaller K, Meling T (2021) Chronic Subdural Hematoma (cSDH): A review of the current state of the art. Brain Spine 1 100300.

[2] Siddiqui F, Al-Mufti F, Dodson V, et al. Consensus Statement on Middle Meningeal Artery Embolization in Chronic Subdural Hematoma Treatment: A Guideline from the Society of Vascular and Interventional Neurology Guidelines and Practice Standards Committee. Stroke: Vascular and Interventional Neurology. 2025;1(1):1-15. Doi:10.1161/SVIN.125.001814.

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