NeurAxis Awarded First Ever FDA Clearance for the Treatment of Pain in Functional Dyspepsia (FD) with associated Nausea Symptoms in the Adult Patient Population

- *Achieves significant expansion of NeurAxis' total addressable market*
- *Clearance now includes patients aged "8 years and older"*
- *Expanded age indication will utilize the upcoming January 1st, 2026, Category I CPT code to report PENFS procedures*

CARMEL, Ind., Oct. 24, 2025 (GLOBE NEWSWIRE) — NeurAxis, Inc. ("NeurAxis," or the "Company") (NYSE American: NRXS), a medical technology company commercializing neuromodulation therapies addressing chronic and debilitating conditions in children and adults, today announced that it has received FDA 510(k) clearance for its proprietary percutaneous electrical nerve field stimulation (PENFS) technology for the treatment of functional abdominal pain (FAP) associated with functional dyspepsia (FD), and FD related nausea symptoms, in patients aged 8 years and older. The FDA reviewed the clinical literature supporting the use of NeurAxis' PENFS technology, including randomized controlled trials and real-world evidence demonstrating the device's safety and effectiveness in pediatric patients and individuals up to 21 years of age. Based on this comprehensive review, the FDA extrapolated the data to adults, supporting the use of PENFS in patients aged 8 years and older. This expanded indication marks a historic milestone, the first FDA clearance or approval for a treatment specifically addressing functional dyspepsia in adults.

"This latest FDA clearance represents a pivotal milestone for NeurAxis as it is the first ever FDA approved or cleared treatment in the adult market for functional dyspepsia which also includes related nausea symptoms," said Brian Carrico, President and Chief Executive Officer of NeurAxis. "By reaching this goal, it will not only broaden our clinical impact but also positions us to drive substantial revenue growth throughout the GI space in all patients 8 years of age and older. Our upcoming January 1st, 2026, Category I CPT Code for PENFS procedures will also apply to this new adult indication, as it is the same device and same technology. This important approval positions NeurAxis as the leader in minimally invasive neuromodulation therapies."

"Functional dyspepsia can include severe abdominal pain and nausea. In both adolescents and adults, the condition can significantly impact quality of life, leading to food avoidance, unintentional weight loss, and restrictive eating behaviors," said Dr. Adrian Miranda, Chief Medical Officer of NeurAxis. "We are thrilled by the agency's decision, which gives us the opportunity to offer the benefit of treatment to thousands of adult patients who have had limited options-until now."

NeurAxis' PENFS technology is a non-surgical device that sends gentle electrical impulses

into cranial nerve bundles in the ear. There are currently no FDA-approved drug therapies for children with abdominal pain-related disorders of the gut-brain interaction (DGBIs) and no approved drug therapies for adults for pain with functional dyspepsia. Pharmacologic treatments that use drugs off-label can often have serious side effects, and most lack scientific evidence of efficacy.

About NeurAxis, Inc.

NeurAxis, Inc., is a medical technology company focused on neuromodulation therapies to address chronic and debilitating conditions in children and adults. NeurAxis is dedicated to advancing science and leveraging evidence-based medicine to drive adoption of its PENFS technology by the medical, scientific, and patient communities. Additional clinical trials of PENFS in multiple pediatric and adult conditions with large unmet healthcare needs are underway. For more information, please visit http://neuraxis.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. There are a number of important factors that could cause actual results, developments, business decisions or other events to differ materially from those contemplated by the forward-looking statements in this press release. These factors include, among other things, the conditions in the U.S. and global economy, the trading price and volatility of the Company's stock, public health issues or other events, the Company's compliance with applicable laws, the results of the Company's clinical trials and perceptions thereof, the results of submissions to the FDA, and factors described in the Risk Factors section of NeurAxis's public filings with the Securities and Exchange Commission (SEC). Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date of this press release and, except to the extent required by applicable law, the Company undertakes no obligation to update or revise these statements, whether as a result of any new information, future events and developments or otherwise.

For Contraindications, Precautions, Warnings, and IFU, please see:

https://ibstim.com/important-information/

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