NeurAxis Inc. Announces FDA 510(k) Clearance of RED for Testing and Evaluation of Patients with Chronic Constipation

RED has been designed to duplicate test performance of traditional balloon expulsion test (BET) and manual sensation testing devices without needing electronics or software.

NeurAxis Inc. will begin the process of commercially marketing RED and expects initial revenues in 1Q25 as there is a Category I CPT code assigned to the procedure and the procedure is covered by Medicare and most commercial insurance companies.

CARMEL, Ind., Dec. 10, 2024 — 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 the US Food and Drug Administration (FDA) granted a 510(k) clearance for RED (Rectal Expulsion Device), allowing NeurAxis to commercially market the device for testing and evaluation of patients with chronic constipation due to pelvic floor dyssynergia and who are unlikely to improve with increased laxative use.

NeurAxis will begin the process of commercially marketing RED and expects a soft launch in the first quarter of 2025 with a full launch expected in the second quarter of 2025. Management believes that providers will be able to bring this clinically beneficial technology to their practice immediately, given its clinical need and total addressable market of roughly $1.5 billion. There is currently a Category I CPT code assigned to the procedure and the procedure is covered by Medicare and most commercial insurance companies.

RED is a proprietary, self-inflating balloon that evaluates a patient's ability to expel contents from the rectum. "For many patients with chronic constipation, traditional laxative therapy does not work well because the problem is not related to colon motility, but rather with the neuromuscular function of the pelvic floor," said Dr. Adrian Miranda, Chief Medical Officer for NeurAxis. "Without proper testing, these patients can be missed and continue to suffer with inadequate treatments." RED can also be used as a qualitative test for rectal hypersensitivity. It will help identify patients who have an exaggerated urge to defecate, which also changes the treatment algorithm for patients with constipation.

"The RED 510(k) clearance is another important achievement as we continue to build and expand our Gastroenterology business and accelerate meaningful revenue growth towards our goal of cash flow breakeven," said Brian Carrico, President and Chief Executive Officer of NeurAxis. "I am excited by our multiple avenues of revenue and profitability growth, driven by the expansion of insurance coverage and age indication of our IB-Stim product for pediatric FAP/IBS and our commercial launch of RED. Looking out beyond 2025, we are

excited to pursue expanded indications with the FDA, using our PENFS technology, including adult FAP/IBS and pediatric/adult Functional Dyspepsia," Mr. Carrico concluded.

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 the adoption of its IB-Stim™ therapy, which is its proprietary Percutaneous Electrical Nerve Field Stimulation (PENFS) technology, by the medical, scientific, and patient communities. IB-Stim™ is FDA-cleared for functional abdominal pain associated with irritable bowel syndrome (IBS) in adolescents 11-18 years old. 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, the results of the shareholder vote to enable the issuance of the Preferred Stock, 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.

Contacts:

Company
NeurAxis, Inc.
info@neuraxis.com

Investor Relations
Lytham Partners
Ben Shamsian
646-829-9701
shamsian@lythampartners.com