NeurAxis Highlights Two Independent Studies Showing Benefits of IB-Stim in Adolescents Involving the Gut Microbiome

CARMEL, Ind., Aug. 22, 2023 — NeurAxis, Inc. (NYSE American: NRXS), ("NeurAxis," or the "Company"), a medical technology company commercializing neuromodulation therapies that address chronic and debilitating conditions in children and adults, today highlights two recently published independent studies showing that IB-Stim therapy leads to improvements in abdominal pain and disability in adolescents with IBS and that the gut microbiome may play an important role.

The publications, *"The microbiome in adolescents with irritable bowel syndrome and changes with percutaneous electrical nerve field stimulation[1]," and "Impact of auricular percutaneous electrical nerve field stimulation on gut microbiome in adolescents with irritable bowel syndrome: a pilot study[2]," authored by Geetanjalo Bora, et al,* both highlight the effect of the gut microbiome in the treatment of adolescents with IBS using IB-Stim, NeurAxis's proprietary technology.

Dr. Adrian Miranda, Chief Medical Officer of NeurAxis said, "We are not surprised by the clinical responses to treatment in either of the studies since we have seen it consistently in all previous studies, including the double-blind, sham controlled, clinical trial by Kovacic, et al published at the Lancet[3]. The fascinating thing, however, is that for the first time, we now have evidence that the microbiome may be modulated by treatment and that the presence of certain microbes may impact the response to therapy. It confirms what we believed since IB-Stim also targets vagal pathways." Dr. Miranda added, "This is yet another indicator that we are in fact targeting the underlying pathophysiology of pediatric IBS through modulation of the gut-brain axis."

Investigators from Cincinnati Children's Hospital, led by Dr. Castillo, collected stool samples from healthy controls and from a cohort of children and adolescents with irritable bowel syndrome (IBS). Those with IBS were treated with IB-Stim™ for 4 weeks. Follow-up assessments were done after 3 months (including repeat stool sample collection). After treatment with IB-Stim, there were significant improvements in abdominal pain, functional disability, and catastrophizing. Bacterial species in the Clostridiaceae family were more abundant in IBS patients compared to healthy control group. After treatment with IB-Stim, there were notable decreases in the clostridial species which have previously been implicated in gastrointestinal pro-inflammatory states. Also, noted after treatment was a decrease in bacterial pathways of long-chain fatty acid synthesis, suggesting modulation of the microbiome and perhaps related inflammation.

Separately, a group of investigators from Children's Wisconsin led by Dr. Bora, also treated children with IBS with 4 weeks of IB-Stim and collected stool samples. Follow-up assessments

showed improvements in IBS severity, visceral sensitivity and functional disability. Subjects with excellent therapeutic response showed an enrichment of and relative abundance of a bacterial species called Blautia, which has been previously used as a probiotic. According to the authors, “this suggests that patients with a specific microbial signature have a more favorable response to therapy.”[2]

Notes:

[1]https://pubmed.ncbi.nlm.nih.gov/37092330/

[2]https://pubmed.ncbi.nlm.nih.gov/37448237/

[3]https://pubmed.ncbi.nlm.nih.gov/28826627/

Forward-Looking Statements

This document contains certain “forward-looking statements”. All statements other than statements of historical fact are “forward-looking statements” for purposes of federal and state securities laws, including, but not limited to, any projections of earnings, revenue or other financial items; any statements of the plans, strategies, goals and objectives of management for future operations; any statements concerning proposed new products and services or developments thereof; any statements regarding future economic conditions or performance; any statements or belief; and any statements of assumptions underlying any of the foregoing.

Forward-looking statements may include the words “may,” “could,” “estimate,” “intend,” “continue,” “believe,” “expect” or “anticipate” or other similar words, or the negative thereof. These forward-looking statements present our estimates and assumptions only as of the date of this document. Accordingly, readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the dates on which they are made. We do not undertake to update forward-looking statements to reflect the impact of circumstances or events that arise after the dates they are made. You should, however, consult further disclosures and risk factors we include in our filings with the Securities and Exchange Commission.

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 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.

This page discusses ongoing research activities with percutaneous electrical nerve field stimulator (PENFS) technology. Please note, the research being described may include information about technology and intended uses of that technology which have not been reviewed or approved/cleared by the U.S. FDA, and is being provided for informational purposes only. NeurAxis does not recommend or suggest the use of its PENFS IB-Stim device for uses beyond those that are cleared by the U.S. FDA.

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