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Oragenics, Inc. Announces Health and Disability Ethics Committee Submission for Phase IIa Concussion Trial

SARASOTA, Fla., April 09, 2025 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a biotechnology company focused on developing novel intranasal therapies for brain-related conditions, today announced that it has submitted a clinical trial protocol for regulatory review to the Health and Disability Ethics Committee (HDEC) in New Zealand.

This submission marks a critical milestone in advancing the Company's Phase II clinical trial evaluating ONP-002, its proprietary neurosteroid therapy, for the treatment of mild traumatic brain injury (mTBI) or concussion. Pending approval, Oragenics expects to initiate patient enrollment in the region and expand the study's geographic reach. The trial is expected to be conducted at Christchurch Hospital in New Zealand, the largest tertiary, teaching, and research hospital on the South Island. Christchurch Hospital provides a full range of emergency, acute, elective, and outpatient services, and its Emergency Department is one of the busiest in Australasia, treating more than 83,000 patients annually.

"Submitting our HDEC application is a pivotal step toward advancing ONP-002 and addressing the critical need for effective concussion treatments," said Janet Huffman, Interim Chief Executive Officer of Oragenics. "With patient enrollment planned in both Australia and New Zealand, including at Christchurch Hospital—one of the region's leading research institutions—we are hoping to expand our global clinical footprint. We look forward to regulatory feedback and moving closer to bringing this much-needed therapy to patients."

No pharmaceutical therapy is available for treating concussion, an unmet medical need. These clinical trials mark the first time a novel chemical drug entity has been tested for efficacy in this patient population. ONP-002 is designed for intranasal administration, offering a non-invasive and efficient route for drug delivery to the brain. The therapy has demonstrated promising results in preclinical models, reducing inflammation, oxidative stress, and brain swelling associated with concussion. A Phase I clinical study proved the drug to be safe and well-tolerated in healthy human volunteers.

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About Oragenics, Inc.

Oragenics is a biotechnology company focused on developing intranasal therapeutics for neurological disorders, including its lead candidate, ONP-002, for the treatment of mild traumatic brain injury (mTBI) or concussion. The Company is also advancing proprietary powder formulations and intranasal delivery technology to enhance drug administration. For more information, visit www.oragenics.com.

Forward-Looking Statements

This communication contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management’s beliefs and assumptions and information currently available. The words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project” and similar expressions that do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to, those described in our Form 10-K and other filings with the U.S. Securities and Exchange Commission. All information set forth in this press release is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. We do not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, circumstances should change, except as otherwise required by law.



Source: Oragenics