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Oragenics Selects Southern Star Research as Clinical Research Organization for ONP-002 Phase IIa Trial

Strategic CRO Partnership Supports Operational Readiness and Initiation of Upcoming Concussion Study

SARASOTA, Fla., July 31, 2025 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company pioneering intranasal drug delivery for neurological conditions, today announced the selection of Southern Star Research as its Clinical Research Organization (CRO) for the upcoming Phase IIa clinical trial of ONP-002, the company's lead drug candidate for concussion.

Southern Star Research is a globally recognized, full-service CRO with a proven track record in delivering early-phase trials across Australia and Asia-Pacific. Their deep operational expertise, regulatory knowledge, and hands-on site management capabilities will support the execution of Oragenics' randomized, double-blind, placebo-controlled Phase IIa study evaluating ONP-002 in adults with mild traumatic brain injury (mTBI).

"Partnering with Southern Star Research ensures we are leveraging experienced, regionally specialized clinical leadership to advance ONP-002," said Dr James Kelly, Chief Medical Officer of Oragenics. "They bring operational rigor, startup speed, and therapeutic area experience needed to move this important program forward efficiently and cost-effectively."

Southern Star Research Founder & Managing Director, Dr. David Lloyd commented, "We are pleased to be partnering with Oragenics on the development of ONP-002. The Phase IIa study of self-administered Intranasal ONP-002 in subjects with mild Traumatic Brain Injury is a significant milestone for Oragenics and we are excited to manage the ONP-002 program here in Australia, paving the way for a larger Phase IIb program."

With Human Research Ethics Committee (HREC) approval already secured, Oragenics is working closely with Southern Star to complete site selection, finalize investigator agreements, and prepare for trial site initiation. Patient enrollment and dosing are expected to begin shortly.

The company's strategic decision to conduct the study in Australia reflects several advantages:

- Access to streamlined regulatory and ethics approval processes
- Availability of experienced concussion trial sites

- Eligibility for Australia's R&D tax incentive program, enhancing cost-efficiency

ONP-002 is a proprietary intranasal neurosteroid with a novel delivery mechanism designed to enhance drug delivery to the brain while minimizing systemic exposure. In preclinical models, ONP-002 demonstrated reduced brain inflammation, improved memory and cognition, and recovery of sensory-motor function.

The Phase IIa trial will evaluate the safety, tolerability, pharmacokinetics (PK), and early pharmacodynamic (PD) effects of ONP-002 in adults with mTBI.

Janet Huffman, Chief Executive Officer of Orogenics, further commented: "This marks a pivotal step toward initiating our Phase IIa clinical trial, and we remain committed to rapidly advancing this program to address the significant unmet need in concussion treatment. With our study infrastructure nearly in place, we are excited to begin patient enrollment and move one step closer to delivering a therapeutic option for those impacted by mild traumatic brain injury."

About Orogenics, Inc.

Orogenics is focused on developing novel intranasal therapeutics to address unmet needs in neurology. The company's lead candidate, ONP-002, is in clinical development for the treatment of concussion. Orogenics is headquartered in Sarasota, Florida. For more information, visit www.rogenics.com.

About Southern Star Research

Southern Star Research is a privately-owned, full-service CRO headquartered in Sydney, Australia. The company specializes in early-phase clinical development across a range of therapeutic areas, supporting sponsors with local regulatory expertise, high-performing sites, and agile clinical operations.

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, should circumstances change, except as otherwise required by law.

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