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Oragenics Activates Second Site in Phase IIa Clinical Trial of ONP-002 for Concussion and Mild Traumatic Brain Injury.

SARASOTA, Fla., May 05, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology, today announced that Alfred Hospital is now actively enrolling participants in its ongoing Phase IIa clinical trial evaluating ONP-002, the Company's lead candidate for the treatment of concussion and mild traumatic brain injury (mTBI). To date, four patients have been enrolled and dosed at Mackay Base Hospital in Queensland, Australia, the first site activated in the trial.

Concussion and mild traumatic brain injury represent the most prominent neurological condition without an FDA-approved pharmacological treatment. According to the CDC, an estimated 1.7 to 3.8 million people in the U.S. experience traumatic brain injuries annually, with sports and recreational activities among the leading causes.[1] Globally, an estimated 69 million individuals sustain traumatic brain injuries each year. Despite this scale, no pharmacological treatments have been approved — leaving patients, military personnel, athletes, and families without effective options beyond rest and symptom management. If approved by the FDA, we believe ONP-002 would be the first and only pharmacological standard of care for a global concussion market projected to reach over $9 billion by 2030.[2]

The Company's Phase IIa trial is designed to enroll 40 patients who meet enrollment criteria based on CT scan findings, presenting symptoms, and emergency room or hospital admission. Patients receive first dosing within 12 hours of concussion, followed by continued treatment for up to 30 days. The pace of enrollment at Mackay Base Hospital since site activation on March 31, 2026, reflects both strong site readiness and the depth of unmet clinical need in this patient population. ONP-002 is delivered via Oragenics' proprietary intranasal spray-dry powder device.

We believe ONP-002 is a first-in-class intranasal neurosteroid designed to address the underlying biology of brain injury — reducing neuroinflammation, oxidative stress, and cerebral edema — rather than simply managing symptoms. The drug candidate targets the biological cascade triggered by trauma, with the potential to represent a paradigm shift from symptom management to active neurological intervention. The Phase IIa clinical data readout is projected before year-end 2026, and is expected to support the Company's planned investigational new drug (IND) application submission to the FDA, targeting December 31, 2026, for a Phase IIb clinical trial in the U.S.

Janet Huffman, Oragenics' CEO, stated, "Four patients have been dosed at Mackay Base Hospital in less than a month of activation. That is not an accident — it is a reflection of what we have been saying since we started this program: concussion patients have nowhere to turn, and when a trial opens its doors, they walk through them. We are executing against our clinical plan. Two sites are now actively enrolling, and we intend to maintain this pace through the full 40-patient enrollment. For the millions of people who have been told there is nothing that can be done for concussion, we are here to prove otherwise."

ABOUT ONP-002

ONP-002 is an investigational neuroprotective, anti-inflammatory intranasal drug candidate targeting mild traumatic brain injury (mTBI) and concussion. Designed to interrupt biological pathways involved in inflammation, oxidative stress, and swelling following head trauma, ONP-002 has demonstrated safety and tolerability in Phase I clinical trials with zero serious adverse events across all dose levels. The drug candidate utilizes Oragenics' proprietary intranasal delivery platform to enable rapid, targeted brain delivery — potentially representing a paradigm shift from symptom management to active neurological intervention. Oragenics is advancing ONP-002 through Phase IIa clinical trials in Australia, with U.S. Phase IIb trials planned to follow pending FDA investigational new drug application (IND) approval.

ABOUT ORAGENICS, INC.

Oragenics, Inc. is a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology. The Company's lead candidate, ONP-002, is being advanced as a potential first-in-class treatment for concussion and mild traumatic brain injury. Oragenics is progressing ONP-002 through Phase IIa clinical trials in Australia, with U.S. Phase IIb trials planned to follow. The Company believes its intranasal delivery platform has potential applications across multiple neurological conditions. Oragenics is committed to developing innovative therapies that address significant unmet medical needs in neurological care. 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. Statements in this news release concerning the Company's expectations, plans, business outlook or future performance, and any other statements concerning assumptions made or expectations as to any future events, conditions, performance or other matters, are "forward-looking statements." Forward-looking statements include statements regarding the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research, development and regulatory activities and expectations relating to product candidates, including without limitation ONP-002 and our proprietary nasal device; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and the timing, conduct, interim results announcements and outcomes of our clinical trials of our product candidates, including ONP-002 for the treatment of concussion and mTBI. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe," "expect," "anticipate," "intend," "estimate," "project,"

"potential," "may," "will," "could," "should," 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 most recent Form 10-K, Form 10-Q and other filings we make with the U.S. Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. All information we set forth in this press release is as of the date hereof. 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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FOOTNOTES

[1] American Association of Neurological Surgeons; Sports Related Head Injury / CDC TBI Data

[2] Grand Market Research; Concussion Market (2025–2030)

Source: Oragenics, Inc.