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Oragenics, Inc. Announces Approval to Initiate Phase II Concussion Drug Trial in Australia

SARASOTA, Fla., May 13, 2025 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a biotechnology company focused on developing novel intranasal therapies for brain-related disorders, today announced that it has received approval from the Human Research Ethics Committee (HREC) in Australia to initiate its Phase II clinical trial evaluating ONP-002, the Company's proprietary neuroprotective therapy, for the treatment of mild traumatic brain injury (mTBI), aka concussion.

This approval marks a significant milestone in expanding Oragenics' clinical development efforts internationally. With this clearance, Oragenics can initiate clinical trials in Australia and could begin patient enrollment as early as the second quarter of 2025. Once the Company is prepared to commence enrollment, patient enrollment and treatment administration is expected to occur in level 1 trauma emergency departments where concussed patients are often seen following motor vehicle accidents, falls, and contact sports

"Receiving HREC approval in Australia brings us one step closer to offering a much-needed therapeutic option for patients suffering from concussions," said Janet Huffman, Chief Executive Officer of Oragenics. "With enrollment sites considered in both Australia and New Zealand, we are significantly expanding the geographic footprint of our ONP-002 program as we move this critical drug trial forward."

ONP-002 is designed for intranasal administration, offering a non-invasive and efficient route for drug delivery to the brain. In preclinical models, ONP-002 has demonstrated the ability to reduce inflammation, oxidative stress, and brain swelling associated with concussion. A Phase I clinical trial showed ONP-002 to be safe and well-tolerated. ONP-002 is being positioned as a promising potential acute therapy for this widespread condition.

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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