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Oragenics, Inc. Prepares Intranasal Pharmaceutical, ONP-002, for Phase II Concussion Trial

SARASOTA, Fla., May 16, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a pioneering pharmaceutical company specializing in intranasal treatments for neurological disorders, today announced an update on the company and its drug development program. Oragenics is designing an upcoming Phase II clinical trial conducted in acute and emergency departments. The company is preparing to initiate a Phase II clinical trial for its lead drug candidate, ONP-002, an innovative neurosteroid designed to treat mild Traumatic Brain Injury (mTBI), commonly referred to as concussion.

Advancements in Drug Formulation for Phase II Trial
Oragenics is focused on enhancing the formulation of ONP-002 by increasing the percentage of active compound in the final spray-dried intranasal powder. The formulation improvements aim to optimize the size of the emitted particles, ensuring they are large enough to prevent deep lung inhalation while maximizing intranasal absorption and brain targeting. This intranasal delivery method is crucial for bypassing the blood-brain barrier, facilitating rapid and efficient drug delivery to the brain within minutes.

Clinical Trial Preparations
In preparation for the Phase II clinical trial, Oragenics has secured an adequate supply of intranasal devices. The company has also partnered with Avance Clinical Pty Ltd, a renowned Clinical Research Organization (CRO) based in Adelaide, Australia. This collaboration will facilitate the implementation of the Phase IIa trial in emergency departments at level one trauma centers, which Oragenics anticipates will result in a robust and well-structured study.

Leadership Insights
“We are privileged to collaborate with exceptional GMP pre-clinical research teams dedicated to optimizing our drug formulation and intranasal device components,” stated Michael Redmond, President of Oragenics. "Our continued partnership with Avance Clinical has been instrumental in ensuring a seamless transition into our Phase II clinical trial.”

Preclinical studies have demonstrated that ONP-002 significantly improves molecular and behavioral outcomes following brain injury. Additionally, intranasal delivery of ONP-002 as a nanoparticle has shown enhanced brain exposure and metabolism, underlining the potential of this innovative treatment.

Dr. James Kelly, Chief Medical Officer of Oragenics, added, “Our Phase I human study has

confirmed that ONP-002 is well tolerated in humans. We are encouraged by the progress and support we have received in optimizing our program, setting the stage for the launch of our Phase II trials."

Addressing an Unmet Medical Need
Concussion remains an unmet medical need, with an estimated 69 million cases reported globally each year. Common causes include falls, motor vehicle accidents, and contact sports. Concussions are also associated with long-term neurological disorders such as Alzheimer's Disease, Parkinson's Disease, and Chronic Traumatic Encephalopathy (CTE). Post-concussion syndrome, which can lead to long-term disability, affects up to 20% of patients with concussion.

Oragenics remains committed to advancing its groundbreaking intranasal pharmaceutical solutions, aiming to provide effective treatments for neurological disorders and to improve patient outcomes worldwide.

About Oragenics, Inc.
Oragenics is a development-stage biotechnology company focused on nasal delivery of pharmaceutical medications in neurology and fighting infectious diseases, including drug candidates for treating mild traumatic brain injury (mTBI), also known as concussion, and for treating Niemann Pick Disease Type C (NPC), as well as proprietary powder formulation and an intranasal delivery device. For more information, please 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, including without limitation statements regarding the ability of the Company to timely and successfully undertake Phase II clinical trials using its novel drug-device combination for the treatment of mild Traumatic Brain Injury. 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: the Company's ability to advance the development of its product candidates, including the neurology assets, under the timelines and in accord with the milestones it projects; the Company's ability to raise capital and obtain funding, non-dilutive or otherwise, for the development of its product candidates; the regulatory application process, research and development stages, and future clinical data and analysis relating to its product candidates, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the Company's ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the nature of competition and development relating to concussion treatments; the Company's expectations as to the outcome of preclinical studies and clinical trials and the potential benefits, activity, effectiveness and safety of its product candidates including as to administration, transmission, manufacturing, storage and distribution; and general economic and market conditions and risks, as well as other uncertainties described in our filings with the U.S. Securities and Exchange Commission. All information set forth is as of the date

hereof unless otherwise indicated. You should consider these factors in evaluating the forward-looking statements included 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.

Oragenics, Inc.
Janet Huffman, Chief Financial Officer
813-286-7900
jhuffman@oragenics.com

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