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Oragenics Inc. Completes Spray Dry Drug Manufacturing and Intranasal Device Filling in Anticipation of Phase IIa Clinical Trial in Concussed Patients

• Falls and car accidents lead incidence of concussions in emergency departments

• Spray-dried drug formulation allows for easy delivery to patients

• No pharmaceutical treatment is available for concussion; drug, ONP-002, could be first of its kind to treat concussion

SARASOTA, Fla., Aug. 21, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN) ("the Company"), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced the completion of its spray-dried formulation and filling in the nasal device for its lead candidate, ONP-002, for concussion. ONP-002 is a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity. The prefilled formulation is intended to provide the needed drug-device dosing for the planned Phase IIa clinical trial in concussed patients.

For the trial, the Company produced both placebo and ONP-002 drug for use in the Phase IIa clinical trial to be conducted in Australia. The work included the production of ONP-002 as a spray-dried nanoparticle formulation, loading of the powder in Oragenics' novel breath-propelled intranasal device, and initiating a stability program of both the drug formula alone and within the device. The Phase IIa clinical trial is expected to enroll 40 concussed patients who will receive 1:1 either placebo or the ONP-002 drug, with doses given twice a day for five consecutive days following injury. The trial aims to start treatment within 8 hours of the injury in the emergency department. It is anticipated that patient-reported outcomes and blood biomarkers will be included in the evaluation.

"In preparing for the Phase IIa study, we wanted to ensure that ONP-002 could be formulated as a nanoparticle and delivered intranasally as a powder to improve brain exposure. The anti-inflammatory effects of our novel neurosteroid are designed to reduce negative outcomes after a concussion. We believe the combination of the spray-dried powder in our device is ideal for field delivery, increasing the chances of stopping the neuropathology of a concussive injury early," commented Michael Redmond, President for Oragenics.

About Concussion

Concussion is an unmet medical need. There are an estimated 69 million concussions annually reported worldwide. Common causes of concussion include falls, motor vehicle accidents, and contact sports. Other neurological disorders, including Alzheimer's Disease, Parkinson's Disease, and Chronic Traumatic Encephalopathy (CTE), have been linked to concussion. Post-concussion symptomology is linked to long-term disability and occurs in as high as 20% of concussed patients.

About Oragenics

Oragenics is a development-stage biotechnology company focused on nasal delivery of pharmaceutical medications in fighting infectious diseases and neurological conditions, 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 trial 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.

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