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Oragenics Improves Intranasal Drug Formulation for Treating Concussed Patients

Formulation designed to enhance brain uptake

SARASOTA, Fla., July 10, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced it has developed a new formulation for its novel neurosteroid. Oragenics' lead drug candidate for concussion, ONP-002, is a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity and onward to the brain. A Phase II study in concussed patients is being planned to assess safety and feasibility while analyzing the drug's effectiveness based on patient blood biomarker profiles and functional outcomes.

Oragenics believes the nasal cavity provides access for Oragenics' novel neurosteroid formulation to enter the brain in minutes. Given the difficulty of getting neurosteroids into solution, unique formulations must be developed to achieve therapeutic levels. Oragenics believes that its recent work has increased the final dose levels significantly while also providing for improved intranasal drug adhesion and, thus, longer absorption times. Oragenics believes it has successfully completed an improved formulation of ONP-002 that should significantly increase the bioavailability of the intranasal drug formulation. The enhanced drug percentages in this novel formulation have been developed by Oragenics as part of its platform for acute-field delivery of the drug. Oragenics' newly developed intranasal drug formulation is intended to reduce the duration of initial concussion symptoms and prevent long-lasting symptoms that can be debilitating after a concussion.

"We are thrilled about the recent modifications to our novel intranasal drug formulation. Anything that can be done to drive more chemical protection to the brain during the acute pathological cascade will help reduce negative outcomes in the concussed population," stated Dr. James Kelly, Chief Medical Officer at Oragenics.

Concussion is a serious unmet medical need. There are an estimated 69 million concussions annually reported worldwide. Common causes of concussion include falls, motor vehicle accidents, military incidents, 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 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 intranasal formulations and intranasal devices for delivering the intranasal formulations. 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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