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Oragenics Inc. Announces Concussion Drug, ONP-002, Successfully Clears FDA-Required Cardiotoxicity Testing

The potential addressable market opportunity for ONP-002 includes an estimated 69 million concussions globally

SARASOTA, Fla., Aug. 08, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced its lead candidate for treating concussion successfully completed a study that indicates ONP-002 does not cause cardiotoxicity. ONP-002 is a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity and onward to the brain. Prior to conducting a clinical trial, the U.S. Food and Drug Administration (FDA) requires pharmaceuticals to be tested on cardiac receptors to ensure that they do not show any causes of electrical malformations.

Oragenics conducted hERG (human Ether-à-go-go-Related Gene) ion channel studies on ONP-002 under Good Laboratory Practices (GLP) with Charles River Laboratories. Like previous non-GLP hERG studies, inhibitory concentrations were greater than 10 micromolar. Based on Phase I ONP-002 clinical trial dosing and subsequent blood plasma concentrations, ONP-002 is expected to have a large cardiac safety margin, suggesting that ONP-002 treatment for concussion will not cause cardiac arrhythmia.

“We are pleased that ONP-002 has demonstrated a strong safety margin for the heart, enabling us to continue planning the Phase II trials. Safety remains our top priority, and we will continuously monitor all safety parameters throughout the trials,” stated Michael Redmond, President of Oragenics. “Furthermore, a Phase II study is being planned to further evaluate the drug in concussed patients.”

Concussion is a significant unmet medical need, with an estimated 69 million cases reported annually worldwide. Common causes of concussions include falls, motor vehicle accidents, and contact sports. According to the CDC, the total annual healthcare cost for nonfatal traumatic brain injuries (TBIs) exceeds $40.6 billion. This includes $10.1 billion covered by private insurance, $22.5 billion by Medicare, and $8 billion by Medicaid. Concussions have been associated with other neurological disorders, such as Alzheimer’s Disease, Parkinson’s Disease, and Chronic Traumatic Encephalopathy (CTE). Additionally, post-concussion symptoms, which can occur in up to 20% of affected individuals, are linked to long-term disability.

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 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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