August 12, 2024

Oragenics, Inc. Announces Concussion Drug Successfully Completes FDA-Required Genotoxicity Study

– ONP-002 showed no cancer-causing DNA damage

– Phase II clinical trial being planned

SARASOTA, Fla., Aug. 12, 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, ONP-002, successfully completed a study that indicates it does not cause DNA damage and genotoxicity in an animal model. 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 that pharmaceuticals be tested on cells and animals to ensure they do not cause damage affecting cell division.

Oragenics conducted an *in vivo* (animal) study to determine if multi-day treatments of ONP-002 cause DNA damage and increased risk of cancer. Three concentrations of ONP-002 were used at a low, medium and high dose. Animal bone marrow was dissected and analyzed for DNA damage. The results showed no evidence of genetic mutations, suggesting that ONP-002 does not affect the cell cycle and therefore does not disrupt cell division that could be cancer-causing. Oragenics partnered with VivoPharm, Inc. to conduct this study under Good Laboratory (GLP) conditions. These results suggest that multi-day treatment for concussion using ONP-002 will not cause genotoxicity.

“We continue to be pleased with the safety profile of ONP-002. We have now shown a safety margin in our two-species toxicology program, cardiac safety with GLP hERG testing and no issue with cancer-causing DNA damage using the *in vivo* micronucleus assay. Oragenics strongly believes that ONP-002 will be safe for concussed patients in our planned Phase II clinical trial. We will continue to monitor systemic and intranasal safety parameters throughout the drug development program,” commented Michael Redmond, President of Oragenics.

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 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.

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

Investor Relations:
Rich Cockrell
CG Capital

404-736-3838
ogen@cg.capital

Source: Oragenics