May 22, 2024

Oragenics Appoints William “Frank” Peacock MD as Chief Clinical Officer

Dr. Peacock to Oversee Upcoming Phase II Clinical Trial for Treating Concussion in the Emergency Department

SARASOTA, Fla., May 22, 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 appointed Dr. William “Frank” Peacock as its Chief Clinical Officer, who will conduct its anticipated Phase II clinical trial for treating concussion in the Emergency Department (“ED”). Oragenics’ lead drug candidate, ONP-002, is combined with its intranasal device intended for the treatment of mild Traumatic Brain Injury (mTBI), commonly known as concussion, in the field and emergency departments. 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 40-patient Phase I study was completed and showed the drug to be safe and well-tolerated.

Dr. Peacock is currently the Vice Chair for Emergency Medicine Research at Baylor College of Medicine and a past Professor at the Cleveland Clinic Lerner College of Medicine. He is also the Principal Investigator of a trial for a company developing blood biomarkers for the identification of concussion in the emergency department, which is analyzing acute blood markers that are elevated after concussion to not only ensure concussion is identified but also as a predictor of potential severity and longer-term complications. Dr. Peacock is a world-renowned speaker and researcher. He has been instrumental in the approval and use of high sensitivity blood troponins for acute coronary syndrome failure in emergency settings, which can be seen in the *JAMA* Cardiology publication, *Efficacy of High-Sensitivity Troponin T in Identifying Very-Low-Risk Patients with Possible Acute Coronary Syndrome* , and he is the editor of the first book of “Biomarkers of Traumatic Brain Injury”.

“I am excited to join Oragenics as its Chief Clinical Officer at such an important and pivotal time in the company’s clinical program. I have been involved with concussion care in the emergency department throughout my 30-plus-year career. My role with the HeadSMART blood biomarker trial has shown me that we need biomarkers to trigger a treatment in the ER. We are searching for that treatment, and I am looking forward to testing ONP-002 to help determine if it can improve patient outcomes in our upcoming Phase II clinical trials,” said Dr. Peacock.

“We are fortunate to have such an esteemed emergency medicine physician and researcher join our team in this important role at Oragenics. Given his understanding of blood biomarkers, throughout his career, his intimate knowledge in emergency medicine protocols and close ties with leading enrollment centers for TBI clinical research, we believe he will

play an invaluable role in the success of Oragenics and planned Phase II trials. We are currently working with Avance Clinical, CRO, for our Phase II trial," stated Michael Redmond, President of Oragenics.

In preclinical animal models, ONP-002 has been shown to acutely improve molecular and behavioral outcomes following brain injury. In addition, intranasal delivery of the drug as a nanoparticle has been shown to enhance brain exposure and metabolism in animals. "Our Phase I human study has shown ONP-002 to be well tolerated in humans. The Phase II trial is designed to establish a time to first dose, relationships between drug application and blood biomarker levels, and the evaluation of patient symptom severity in the first few hours and days after injury," said Dr. Peacock.

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 syndrome 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

Source: Oragenics