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Oragenics Inc. Successfully Completes Key FDA-Recognized Study for ONP-002

SARASOTA, Fla., Oct. 08, 2024 (GLOBE NEWSWIRE) -- Oragenics Inc. (NYSE American: OGEN), a company focused on developing new treatments for brain-related health conditions, has completed a key study for their new concussion drug, ONP-002. This drug is designed to be delivered through the nose, which could help it reach the brain quickly after a head injury.

The recent study shows that the drug successfully targets areas inside the nose that are connected to the brain. This makes it more likely to reach and treat the brain after a concussion. Intranasal casting studies are valued by the FDA for pharmaceuticals delivered via the nasal passage and accept such studies in FDA submissions. Oragenics is now preparing to move forward with human testing (Phase II) in patients who come to the emergency room with a concussion, aiming to give the first dose of the drug within 8 hours of the injury.

"In preparing for our Phase II study, we wanted to study whether our nasal spray device would give ONP-002 an increased chance of reaching the brain quickly after a concussion. The study results are promising, as they show the drug targets areas in the nose directly linked to the brain. This should increase the chances of the drug being effective in treating concussion and reduces the likelihood of it being swallowed, which is another encouraging sign," said Michael Redmond, President of Oragenics.

In this study, ONP-002 was tested using a special nasal spray device. The goal of intranasal casting studies is to identify where the drug lands inside an anatomical model of the interior nose that is made from cast metal (AINI). The model is standard for intranasal drug delivery and is accepted by the FDA as a surrogate for the actual nasal passage. The results were promising, showing that the drug spreads well in the areas of the nose where it can be quickly absorbed into the brain. This makes it a strong candidate for potentially helping people recover from concussions.

Concussions are a common problem, with around 69 million people affected every year. Many concussions happen due to falls, car accidents, or sports injuries, and long-term symptoms can develop in up to 20% of patients. Currently, there is no pharmaceutical treatment for concussions, which is why Oragenics' work is so important.

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.

About Nasal Casting

The FDA values studies on nasal drug delivery systems and accepts them in submissions for pharmaceuticals that use the nasal passage. These studies are critical for assessing the bioavailability and bioequivalence of drugs, particularly nasal aerosols and sprays. The FDA's guidance on bioavailability and bioequivalence emphasizes the use of in vitro and in silico methods (like computational simulations) to assess how drugs are deposited and distributed within the nasal cavity. These methods help ensure that both new drug applications (NDAs) and abbreviated new drug applications (ANDAs) meet regulatory requirements.

Reference Links:

- [Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.](#)
- [Computational Simulations Shed Light on Factors Affecting Nasal Spray Distribution.](#)

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. 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, those described in our Form 10-K and other filings with the U.S. Securities and Exchange Commission. All information set forth in this press release is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this press release 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, circumstances should change, except as otherwise required by law.

Investor Relations:

Rich Cockrell

404.736.3838

achv@cg.capital



Source: Oragenics