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Oragenics Reports Favorable Toxicology Results for its COVID-19 Intranasal Vaccine Candidate

No toxicity found in NT-CoV2-1, supports regulatory filing for Phase 1 study

TAMPA, Fla.--(BUSINESS WIRE)--

Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company"), a biotechnology company dedicated to fighting infectious diseases including COVID-19, today announced results indicating no toxicity signals or adverse events from its Good Laboratory Practices (GLP) toxicology study in rabbits evaluating the safety and immunogenicity of its NT-CoV2-1 intranasal vaccine candidate. Oragenics believes the findings of the final toxicology report, including a full histopathology evaluation, confirm a safety and immunogenicity profile that further support its plan to submit regulatory filings required to progress to a Phase 1 clinical study.

"There is an unmet medical need for an intranasally administered COVID-19 vaccine. We are encouraged by these favorable toxicology study results, which advance the preclinical work required for pursuing regulatory permission to begin human testing. This marks an important milestone in the progress of bringing an intranasal COVID-19 vaccine to the market," said Kim Murphy, President and Chief Executive Officer of Oragenics. "Signals of adequate immune responses have been demonstrated in prior preclinical studies with NT-CoV2-1 against multiple SARS-CoV-2 variants of interest. We expect to provide an update on our regulatory pathway in the first quarter of 2023."

The objectives of the toxicology study were to evaluate the potential toxicity of NT-CoV2-1 following repeated intranasal administration at the maximal dose anticipated to be used in humans, and to confirm the immunogenicity of the vaccine.

Oragenics previously published positive preclinical data in *Scientific Reports*, a Nature journal, demonstrating that intranasal administration of NT-CoV2-1 induced robust antigen-specific IgG and IgA titers in the blood and lungs of mice, and reduced viral load below the limit of detection in a hamster SARS-CoV-2 challenge model. In both mice and hamsters, the antibodies had strong neutralizing activity, preventing the cellular binding of the viral spike protein based on the ancestral reference strain and variants of concern.

About Oragenics, Inc.

Oragenics, Inc. is a development-stage company dedicated to fighting infectious diseases, including those caused by coronaviruses and multidrug-resistant organisms. Its lead product

is NT-CoV2-1, an intranasal vaccine candidate to prevent COVID-19 and variants of the SARS-CoV-2 virus. The NT-CoV2-1 program leverages coronavirus spike protein research licensed from the National Institutes of Health (NIH) and the National Research Council of Canada (NRC) with a focus on reducing viral transmission and offering a more patient-friendly intranasal administration. Its lantibiotics program features a novel class of antibiotics against bacteria that have developed resistance to commercial antibiotics. For more information about Oragenics, 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. 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 following: the Company’s ability to advance the development of its vaccine candidate and lantibiotics candidate under the timelines and in accord with the milestones it projects; the Company’s ability to obtain funding, non-dilutive or otherwise, for the development of the vaccine and lantibiotic product candidates, whether through its own cash on hand, or another alternative source; the regulatory application process, research and development stages, and future clinical data and analysis relating to vaccines and lantibiotics, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the potential application of our vaccine candidate to variants and other coronaviruses; the Company’s ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the nature of competition and development relating to COVID-19 immunization and therapeutic treatments and demand for vaccines and antibiotics; the Company’s expectations as to the outcome of preclinical studies, nasal administration, transmission, manufacturing, storage and distribution; other potential adverse impacts due to the global COVID-19 pandemic, such as delays in regulatory review, interruptions to manufacturers and supply chains, adverse impacts on healthcare systems and disruption of the global economy; 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 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, should circumstances change, except as otherwise required by law.

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