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Oragenics' SARS-CoV-2 Spike Protein Produces Neutralizing Antibodies in Mice with Intramuscular and Intranasal Adjuvants

New data supports Company's approach to COVID-19 vaccine development.

TAMPA, Fla.--(BUSINESS WIRE)-- **Oragenics, Inc. (NYSE American: OGEN)** (the Company) announces that the stabilized pre-fusion spike protein trimer produced by its Canadian collaborator and licensed by the Company from the National Institutes of Health (NIH) generates neutralizing antibodies in mice after immunization against SARS-CoV-2, when administered with several novel intramuscular (IM) and intranasal (IN) adjuvants. The expression platform, developed with support from Oragenics' Canadian collaborator, will expedite the evaluation of hybrid SARS-CoV-2 antigen candidates that are scheduled to be evaluated in a hamster viral challenge study beginning with dosing at the end of this month. The mouse immunogenicity study enabled the down-selection of the four adjuvant candidates tested thus far, with two being advanced to assess inhibition of viral replication in hamsters, and IND-enabling toxicology studies. A manuscript suitable for publication, inclusive of the mouse data, will be prepared upon completion of the hamster study.

"We are delighted that our SARS-CoV-2 spike protein produced with the high-throughput expression platform from our collaborator shows promise in the development of a next-generation COVID-19 vaccine, and believe this research affirms our development strategy with Oragenics' lead vaccine candidate, Terra CoV-2," said Fred Telling, Ph.D., Executive Chair of Oragenics. "We are pleased to see a robust immunological response with both our novel IM and IN adjuvants. Additionally, we are optimistic about the pre-clinical intranasal data given the respiratory route of transmission of the SARS-CoV-2 virus, and the prospect of developing a novel vaccine candidate that has the potential to reduce viral transmission. The data substantiates our choice of adjuvants to use in subsequent animal and ultimately human studies. We expect to file an IND application with the FDA in the first quarter of 2022."

Dr. Telling concluded, "Oragenics continues to believe that our licensed platform will improve development speed, while the ability to rapidly engineer new vaccine antigens will permit us to quickly address new variants as they arise, which will be key in the event that SARS-CoV-2 becomes a seasonal flu-like disease, as many experts anticipate will be the case."

About Oragenics, Inc.

Oragenics, Inc. is a development-stage company dedicated to fighting infectious diseases including coronaviruses and multidrug-resistant organisms. Its lead product is Terra CoV-2, a vaccine candidate to prevent COVID-19 and variants of the SARS-CoV-2 virus. The Terra CoV-2 program leverages coronavirus spike protein research licensed from the NIH and the NRC with a focus on addressing supply-chain challenges, and offering more patient-friendly administration, such as intranasal. Its lantibiotics program features a novel class of antibiotics against bacteria that have developed resistance to commercial antibiotics.

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 Terra CoV-2 and lantibiotics 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 product candidate, Terra CoV-2 and our lantibiotics, 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 Terra CoV-2 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 Terra CoV-2 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 administration, 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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