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Oragenics Announces Positive Results from Confirmatory Animal Study of AG013 for Treatment of Oral Mucositis and Plans to Finalize Phase 2 Clinical Trial Protocol

A new approach for patients suffering from side effects of their cancer treatment

TAMPA, Fla.-- [Oragenics, Inc.](#) (NYSE MKT: OGEN) today announced positive results from a confirmatory animal study supporting previous findings of a Phase 1b clinical trial for the prevention and treatment of oral mucositis (OM). Data from the Phase 1B trial published in the journal [Cancer](#) showed AG013 was safe, well tolerated, and demonstrated preliminary efficacy with a 35% reduction in the duration of ulcerative OM compared to placebo.

Having completed this confirmatory study, Oragenics has initiated regulatory as well as CMC activities to further advance the AG013 program and expects to finalize a Phase 2 Clinical Trial Protocol in the near future in anticipation of meeting with the U.S. Food and Drug Administration (FDA).

Dr. Frederick Telling, Oragenics' Chairman, said, "We are pleased by the confirmatory study's results, and we will use them as we move toward a meeting with the FDA with the goal of launching a major Phase 2 trial on AG013 targeting a reduction of the duration and severity of oral mucositis in head and neck cancer patients."

OM is a painful condition associated with chemoradiotherapy treatment of head and neck cancers which results in inflammation, ulceration, and lesion formation in the oral cavity, throat, and esophagus. Affecting up to 500,000 patients annually, OM is among the most frequently reported adverse events associated with cancer therapy. Oragenics is pursuing development of AG013 under an Exclusive Channel Collaboration with [Intrexon Corporation](#) (NYSE: XON).

"Oral mucositis caused by radio- or chemotherapy is a devastating and common side effect which impacts patients' ability to tolerate treatment. The lack of an effective intervention for oral mucositis negatively affects patients, frustrates caregivers and increases the overall cost of treatment. These results confirm the earlier pre-clinical and clinical studies of AG013's efficacy and provide a continued rationale for moving forward aggressively with a Phase 2 trial," said Stephen T. Sonis, DMD, DMSc, Senior Surgeon, Divisions of Oral Medicine, Brigham and Women's Hospital and the Dana-Farber Cancer Institute and Chief Scientific Officer of Biomodels, LLC.

Samuel Broder, M.D., Senior Vice President and Head of Intrexon's Health Sector, stated,

"Oral mucositis has a significant impact on the quality of life for the many head and neck cancer patients undergoing treatment, and current therapies are primarily palliative, only alleviating symptoms. We look forward to the continued development of AG013 by our ECC partner, Oragenics, to provide a treatment that addresses the underlying pathology of those who suffer with this condition."

About Oragenics, Inc.

We are focused on becoming the world leader in novel antibiotics against infectious disease. We also develop, market and sell proprietary probiotics specifically designed to enhance oral health for humans and pets and on developing effective treatments for oral mucositis. Oragenics, Inc. has established two exclusive worldwide channel collaborations with Intrexon Corporation, a synthetic biology company. The collaborations allow Oragenics access to Intrexon's proprietary technologies toward the goal of accelerating the development of much needed new antibiotics that can work against resistant strains of bacteria and the development of biotherapeutics for oral mucositis and other diseases and conditions of the oral cavity, throat, and esophagus. Oragenics also develops, markets and sells proprietary OTC probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora both in the United States and through the use of distributors in locations outside of the United States.

For more information about Oragenics, www.oralgenics.com.

Safe Harbor Statement: Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements that reflect management's current views with respect to future events and performance. 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, our current need for financing to meet our operational needs and to be able to move our product candidates forward through pre-clinical and clinical development, our inability to obtain sufficient financing to conduct our business; any inability to obtain or delays in FDA approval for future clinical studies and testing, the future success of our studies and testing and any inability to also achieve favorable results in human studies, our ability to successfully develop and commercialize products, the financial resources available to us to continue research and development, and those other factors described in our filings with the U.S. Securities and Exchange Commission. Any responsibility to update forward-looking statements is expressly disclaimed.

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