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Oragenics Doses First Patient in Phase 2 Clinical Trial of AG013 for Oral Mucositis

TAMPA, Fla.--(BUSINESS WIRE)-- Oragenics, Inc. (NYSE MKT: OGEN), a leader in the development of new antibiotics against infectious diseases and effective treatments for oral mucositis, today announced that the first patient has been dosed in its Phase 2 clinical trial of AG013 for the treatment of oral mucositis (OM).

“We are very excited to dose the first patient and initiate the Phase 2 trial of AG013 for oral mucositis, one of the most common and debilitating complications of chemo-radiation therapies. With no approved preventative treatment, oral mucositis represents a serious unmet need that we hope to help overcome,” said Alan Joslyn, Oragenics’ President and Chief Executive Officer. “The initiation of the trial represents a significant milestone for Oragenics. We expect to report preliminary data on the initial 20 enrolled patients by the end of 2017 with completion and full results of the trial expected by the end of 2018.”

The Phase 2 clinical trial of AG013 is a double-blind, placebo-controlled study that will be conducted at approximately 30 sites across the United States and Europe, and is expected to enroll up to 200 patients. The purpose of the study is to evaluate the efficacy, safety and tolerability of administered AG013 compared to placebo for reducing OM in patients undergoing chemo-radiation for the treatment of head and neck cancer, as measured by the duration, time to development, and overall incidence of OM.

AG013 is an ActoBiotics[®] therapeutic candidate formulated as a convenient oral rinsing solution and designed by our strategic collaboration partner Intrexon Corporation (NYSE: XON) to deliver the therapeutic molecule Trefoil Factor 1 to the mucosal tissues in the oral cavity. Trefoil Factors are a class of peptides involved in the protection of gastrointestinal tissues against mucosal damage and play an important role in subsequent repair. AG013 received Fast Track designation from the U.S. Food and Drug Administration (FDA) in November 2016.

Under an Exclusive Channel Collaboration Agreement with Intrexon, Oragenics has an exclusive worldwide license to develop and commercialize AG013 to treat OM in cancer patients.

About Oragenics, Inc.

We are focused on becoming the world leader in novel antibiotics against infectious disease 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.

For more information about Oragenics, please visit www.oragenics.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 the Food and Drug Administration 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, any inability to regain compliance with the NYSE MKT continued listing requirements 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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Oragenics, Inc.
Michael Sullivan, 813-286-7900
Chief Financial Officer
msullivan@oragenics.com

or

Investor/Media Relations
The Ruth Group
Tram Bui, 646-536-7035
tbui@theruthgroup.com

Source: Oragenics, Inc.