December 2, 2019

Oragenics, Inc. Announces Completion of Enrollment of Its Phase 2 Clinical Trial for AG013 in Oral Mucositis

TAMPA, Fla.--(BUSINESS WIRE)-- Oragenics, Inc. (NYSE American: OGEN), a leader in the development of new antibiotics against infectious diseases and effective treatments for oral mucositis (OM), today announced the completion of enrollment in its ongoing double-blind, randomized, placebo-controlled Phase 2 trial of its lead product candidate, AG013, an easy to use oral rinsing system designed to prevent and treat OM.

The ongoing Phase 2 trial is a double-blind, placebo-controlled, two-arm, multi-country, multi-center trial, in which 200 patients have been randomized in a 1:1 ratio to receive either AG013 (“*dapatifagene navolactibac”)* or a placebo. The purpose of the study (NCT03234465) is to evaluate the safety, tolerability and efficacy of topically administered AG013 compared to placebo for reducing the incidence and severity of OM in patients undergoing traditional chemoradiation (CRT) for the treatment of head and neck cancer (HNC). Key measures include duration, time to development, and overall incidence of OM (using a World Health Organization (WHO) scale) during the active treatment phase, which begins from the start of chemoradiation therapy and ends two weeks following its completion.

Alan Joslyn, Ph.D., President and Chief Executive Officer of Oragenics, stated, “The completion of enrollment represents the next key operational milestone in the continued progress toward completion of this important clinical trial evaluating the clinical efficacy and safety of our AG013 product candidate. Oral mucositis is a debilitating condition in head and neck cancer patients receiving chemoradiation and it is our belief that AG013 will provide relief for patients at risk for development of this condition and allow them to successfully complete their cancer treatment regimen.” Dr. Joslyn continued, “With the achievement of this significant corporate milestone, we remain on track to report results from this study in early 2020.”

OM results in a painful inflammation and mucosal ulceration in the lining of the oral cavity, throat and esophagus and is one of the most commonly reported adverse events associated with cancer chemotherapy and radiation therapy. Approximately 770,000 patients annually in the U.S. are at an increased risk of developing OM according to cancer statistics provided by the Center for Disease Control in 2017. OM has a negative effect on patient well-being and, if severe, negatively affects adherence to a patient’s cancer treatment regimen and adversely impacts a range of collateral health outcomes, all resulting in increased use of resources and cost of care. Virtually all patients who receive standard concomitant CRT regimens for the treatment of HNCs develop ulcerative OM (UOM: WHO Grade ≥2). Even more significant is

the consistent observation that severe OM (WHO Grade ≥3) is noted in more than two-thirds of the same patient population. At present, there are no drugs approved to prevent the condition broadly and current therapies are primarily palliative in nature, only addressing symptom relief but not treating the underlying causes of the condition.

About AG013

AG013, which has been granted Fast Track designation with the U.S. Food and Drug Administration and orphan drug status in Europe, is an ActoBio Therapeutics Inc. candidate formulated to deliver the therapeutic molecule, human Trefoil Factor 1, to the mucosal tissues in the oral cavity in a convenient oral rinsing solution system. Trefoil Factors are a class of peptides involved in the protection of gastrointestinal tissues against mucosal damage and play an important role in these tissues' subsequent regeneration. The human Trefoil Factor1 is delivered to the oral cavity using a genetically modified *Lactococcus lacti* bacteria, commonly found in dairy products, engineered to continuously delivery the human protein. The compound was designed by the Company's strategic partner, ActoBio Therapeutics Inc., a wholly-owned subsidiary of Intrexon Corporation (NASDAQ: XON).

About Oragenics, Inc.

We are focused on becoming a 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 and its subsidiaries. The collaborations allow Oragenics to accelerate 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, risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission. Oragenics assumes no responsibility to update any forward-looking statements contained in this press release or with respect to the matters described herein.

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Oragenics, Inc.
Corporate:
Michael Sullivan, 813-286-7900
Chief Financial Officer

msullivan@oragenics.com
or
Investors:
John Marco
Managing Director
CORE IR
310-819-2948
johnm@coreir.com
Media:
Jules Abraham
CORE IR
917-885-7378
julesa@coreir.com

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