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Oragenics, Inc. Resumes Phase 2 Clinical Trial of AG013 in Oral Mucositis Following Positive Routine Safety Review

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 it has resumed its Phase 2 clinical trial of AG013, a *live* biotherapeutic product for the potential treatment of OM following a positive review by an independent Data Safety Monitoring Board (DSMB).

“Based on the DSMB’s positive review, and using funds recently raised through a public offering, we are now expanding our Phase 2 trial to up to 45 additional centers in the US and EU in order to rapidly accelerate patient enrollment,” stated Alan Joslyn, president and CEO of Oragenics, Inc. “With our reinforced cash position, we look forward to completing the trial next year while concurrently advancing our lantibiotic program.”

In May 2018, Oragenics reported positive interim safety analysis results based on the first 19 patients, which were evaluated on the basis of treatment-emergent adverse events, vital signs, weight, physical examination, clinical laboratory assessment and the potential presence of AG013 in blood. Tolerability measures (taste, consistency and smell) were collected from patient diaries. Following a routine data review, the trial’s independent DSMB concluded that it may proceed with no necessary changes to the study.

The ongoing Phase 2 trial is a double-blind, placebo-controlled, two-arm, multi-center trial, in which approximately 200 patients will be randomized in a 1:1 ratio to receive either AG013 or 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 for the treatment of head and neck cancer. Key measures include duration, time to development, and overall incidence of OM (World Health Organization scale) during the active treatment phase, which begins from the start of chemoradiation therapy until two weeks following its completion.

AG013, which has been granted Fast Track designation with the U.S. Food and Drug Administration and orphan drug status in Europe, is an ActoBiotics® therapeutic candidate formulated to deliver the therapeutic molecule Trefoil Factor 1 to the mucosal tissues in the oral cavity in a convenient oral rinsing solution. 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. The compound was designed by the company’s

strategic partner, ActoBio Therapeutics, Inc., a wholly-owned subsidiary of Intrexon Corporation (NYSE: 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 allows 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.
Michael Sullivan, 813-286-7900
Chief Financial Officer
msullivan@oragenics.com
or
CORE IR
Investors:
John Marco, 310-819-2948
Managing Director
johnm@coreir.com
or
Media:
Jules Abraham, 917-885-7378
julesa@coreir.com

Source: Oragenics, Inc.