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## Oragenics, Inc. Provides Development Update of AG013 for Oral Mucositis

*Phase 2 Clinical Trial Enrollment Progresses While World Health Organization Provides Generic Name of AG013 Compound*

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 development updates regarding the Company's lead compound for OM, AG013. These developments include the enrollment of over 80 patients in the Company's Phase 2 clinical of AG013 and, in addition, the World Health Organization has provided the Company with the generic name of *dapatifagene navolactibac* for the AG013 compound.

"We continue to increase the number of clinical sites across the globe with 48 of the 61 identified clinical sites actively enrolling patients for our Phase 2 clinical trial of AG013," stated Alan Joslyn, Ph.D., President and Chief Executive Officer of Oragenics, Inc. "In the meantime, we are pleased to have an agreed upon generic designation for AG013, which will now also be referred to as *dapatifagene navolactibac*, to allow us a more specific way of referring to the compound moving forward. We anticipate providing further updates as developments warrant."

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 *dapatifagene navolactibac* or placebo. The purpose of the study (NCT03234465) is to evaluate the safety, tolerability and efficacy of topically administered *dapatifagene navolactibac* 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 (using a World Health Organization scale) during the active treatment phase, which begins from the start of chemoradiation therapy and ends two weeks following its completion.

*Dapatifagene navolactibac*, which has been granted Fast Track designation with the U.S. Food and Drug Administration and orphan drug status in Europe, is an Intrexon Actobiotics therapeutic 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. 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 compound was designed by the Company's strategic partner, Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon Corporation (NYSE: XON) whereby Oragenics, Inc. holds an exclusive world-wide license.

## 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](http://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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