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Oragenics, Inc. Receives Clearance to Enroll Patients in Germany and the United Kingdom into Its Phase 2 Clinical Trial of AG013 for 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 it has received clearance to enroll patients residing in Germany from the Paul Erlich Institute and patients residing in the United Kingdom from the Medicines and Healthcare products Regulatory Agency (MHRA), into its Phase 2 clinical trial of AG013, a *live* biotherapeutic product for the potential prevention and treatment of OM.

"We are pleased with the receipt of regulatory Health Authority approvals in Germany and the United Kingdom. These approvals provide us with the opportunity to expand the number of clinical trial sites from which we can draw patients to participate in our clinical trial of AG013," stated Alan Joslyn, Ph.D., president and CEO of Oragenics, Inc. Dr. Joslyn continued "The approvals of Germany and the United Kingdom, further enhance our ability to complete the clinical study in 2019."

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 (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.

AG013, 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 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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