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U.S. FDA Grants Fast Track Designation for the Development of Oragenics' AG013 for Oral Mucositis

TAMPA, Fla.--(BUSINESS WIRE)-- Oragenics (NYSE:MKT - OGEN.BC), a leader in the development of novel antibiotics against infectious disease and developing effective treatments for oral mucositis (OM), today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to AG013, the Company's lead therapeutic candidate for the treatment of OM. Oragenics expects to file an Investigational New Drug (IND) update and initiate a Phase 2 study with AG013 in the United States and Europe in early 2017.

Fast Track is a process designed to facilitate the development and review of drugs to treat serious conditions and address key unmet medical needs by allowing for more frequent meetings and communications with the FDA. It also provides eligibility submission of a New Drug Application (NDA) on a rolling basis as well as Accelerated Approval and Priority Review.

"We are pleased that AG013 has received this Fast Track designation which aims to help get important new drugs for unmet clinical needs to patients earlier," said Alan Joslyn, Oragenics' Chief Executive Officer and President. "This is another significant milestone in the path providing a new therapy for cancer patients who develop oral mucositis."

AG013 is an ActoBiotics™ therapeutic candidate formulated as a convenient oral rinsing solution and designed by Intrexon Corporation (NYSE: XON) to deliver the therapeutic molecule Trefoil Factor 1 (TFF1) to the mucosal tissues in the oral cavity. Trefoil Factors are a class of peptides involved in protection of gastrointestinal tissues against mucosal damage and have an important role in subsequent repair. In addition to this Fast Track designation, AG013 has already been granted Orphan Drug status in the European Union.

A Phase 1B clinical trial with AG013 in 25 head and neck cancer patients at high risk for OM demonstrated that AG013 was safe and well tolerated. Data published in the journal *Cancer* showed a 35% reduction in the duration of ulcerative OM in AG013-treated patients versus placebo treated patients. Additionally over 30% of patients treated with AG013 were complete responders, defined as patients who did not develop OM, while all patients receiving placebo developed OM. A Phase 1 pharmacokinetic study in 10 healthy volunteers showed that live AG013 *L. lactis* adhered to the entire oral mucosal surface up to 24 hours after administration of the rinse.

Under an Exclusive Channel Collaboration Agreement with Intrexon, Oragenics has an

exclusive worldwide license to develop and commercialize AG013 to treat oral mucositis in cancer patients.

About Oral Mucositis (OM)

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 affecting up to 500,000 patients annually. OM has a negative effect on patient well-being and if severe, negatively affects a patient's cancer treatment regimen. At present, no drug is 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 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, 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 FDA's approval of 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 and the allocation of such resources among our product candidates: 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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