September 30, 2019

Oragenics Presents Interim Data on The AG013 Phase 2 Clinical Trial at the European Society for Medical Oncology Congress 2019

TAMPA, Fla.--(BUSINESS WIRE)-- Oragenics, Inc. (NYSE American:OGEN) (“Oragenics”), a leader in the development of novel antibiotics against infectious diseases and effective treatments for oral mucositis, today announces initial data from its ongoing Phase 2, placebo-controlled, clinical trial of AG013 in oral mucositis presented in a poster session at the European Society for Medical Oncology (ESMO) Congress 2019 in Barcelona, Spain.

Titled, “Severe oral mucositis (SOM) mitigation by genetically modified Lactococcus lactis bacteria (LLB) producing human trefoil factor 1 (hTFF1; AG013) in patients being treated with concomitant chemoradiation (CRT) for oral and oropharyngeal cancers (OCOPC),” was presented at the ESMO Congress 2019 in Barcelona, Spain. The poster can be found under the “Presentations” tab in the “News and Media” section of the Company's website, located at www.oragenics.com.

The poster presentation describes the methods and initial blinded results from the ongoing Phase 2 clinical trial for the Company’s lead oral mucositis product candidate, AG013. The ongoing Phase 2 clinical 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 three times daily following meals, beginning on the first day of chemoradiation therapy and continuing through the course of cancer treatment. The purpose of this Phase 2 clinical study, (NCT03234465), is to evaluate the efficacy (preventing the occurrence and shortening the duration of SOM), safety, and tolerability of a convenient topically administered rinse of AG013 compared to a placebo for reducing the incidence and severity of oral mucositis in patients undergoing traditional chemoradiation for the treatment of head and neck cancer. The initial data, submitted in the abstract, reflects the results for 42 of the 71 enrolled and randomized patients across 48 study sites and demonstrates that in the blinded, combined placebo and active treatment groups, there was sufficient evidence of efficacy and safety to continue the study.

Additional data accumulated since poster submission, indicates the blinded efficacy evaluation, which included any patient with SOM after week one of treatment and those receiving a cumulative dose of 55 Gy (week 6 of treatment), demonstrated an overall SOM incidence of 47%, which is lower than would be expected based on historical data in the head and neck cancer population receiving this chemoradiation regimen. The overall rate of SOM was reported in only 13.1 % (110 of 842) of evaluable visits. The overall safety profile

is consistent with those adverse events that normally occur in cancer patients receiving chemoradiation therapy. As a reminder, the study remains blinded and individual treatment responses remain to be identified. The lead author for the poster presentation is Suraj Singh, M.D., of the MultiCare Regional Cancer Center in Tacoma, Washington.

Alan Joslyn, President & CEO of Oragenics, Inc. said, “As we recently announced, we are more than 75 percent enrolled in this study, and we continue to be encouraged by both the pace of enrollment and the overall clinical results as reported in this poster presentation. While it remains difficult to comment on efficacy outcomes based on these data, we are pleased with the safety profile we are seeing in the study. Due to the high incidence of SOM in head and neck cancer patients, and the blinded results seen to date, we maintain the belief that this compound will provide a convenient meaningful therapeutic benefit for these patients with limited treatment alternatives and no therapies available for prevention of their oral mucositis.”

About Oral Mucositis

Oral mucositis is currently one of the most common and debilitating complications of cancer chemo- and radiation therapy. The condition is caused by the breakdown of the mucosal lining in the oral cavity resulting in the formation of painful mouth ulcers. When these mouth ulcers progress to World Health Organization (WHO) grade 3 and 4, patients by definition, have their ability to eat (grade 3) and drink (grade 4) impacted resulting in emergency room visits or hospitalization in order to provide pain control and nutritional support. During these periods, patients run the risk of interruption of their chemo- and radiation therapies with the potential risk of negative cancer treatment outcomes. The incidence of SOM is approximately 70% in oropharyngeal cancer patients.

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 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 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.

Forward-Looking Statements

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995, as amended, that involve significant risks and uncertainties about Oragenics, including but not limited to statements with respect to the use of proceeds of the underwritten offering of common stock and warrants. Oragenics may use words such as “expect,” “anticipate,” “project,” “intend,” “plan,” “aim,” “believe,” “seek,” “estimate,” “can,” “focus,” “will,” and “may” and similar expressions to identify such forward-looking statements. Among the important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are risks relating to, among other things, market and other conditions, Oragenics’ business and financial condition, the timing of future clinical trials; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the Company and the impact of general economic, industry or political conditions in the United States or internationally. Oragenics may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management’s current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to meet business objectives and operational requirements, the fact that the results of earlier studies and trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by Oragenics intellectual property, risks related to the drug development and the regulatory approval process and the impact of competitive products and technological changes. For additional disclosure regarding these and other risks faced by Oragenics, see disclosures contained in Oragenics’ public filings with the SEC, including the “Risk Factors” in the company’s Annual Report on Form 10-K, and Quarterly Reports on Form 10-Q. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. The forward-looking statements are made as of the date hereof, and Oragenics undertakes no obligation to update such statements as a result of new information, except as required by law.

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