May 30, 2018

Oragenics Reports Positive Interim Safety Analysis Results from 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 positive results from its interim safety analysis as requested by FDA on patients from its Phase 2 clinical trial of AG013 for the treatment of OM. The study provides information that, we believe, likely indicates that the overall incidence of severe OM is less than would be anticipated in the general population.

The Phase 2 trial is a double-blind, placebo-controlled, 2-arm, multi-center trial in which approximately 200 patients will be randomized in a 1:1 ratio to receive either placebo or AG013. Safety was evaluated on the basis of treatment-emergent adverse events, vital signs, weight, physical examinations, clinical laboratory assessments and the presence of AG013 in whole blood. Tolerability measures (taste, consistency and smell) were collected from the patient diaries. In addition, the reasons for study treatment discontinuation were also summarized. To date, 24 patients have been randomized and 19 patients included in the safety evaluation.

Following review of the data by an independent Data Safety Monitoring Board (DSMB), it was concluded that the clinical trial can proceed with no changes to the study. The data analysis indicated that the distribution of adverse events were similar between AG013 and placebo. The serious adverse events reported were consistent with those commonly reported in a head and neck cancer population receiving traditional chemoradiation therapy treatments and included fevers, neutropenia, anemia, nausea and vomiting, infections and oral (mouth and throat) pain. There were no reports of bacteremia or sepsis. Of patients that discontinued participation in the clinical study, 4 patients experienced adverse events, including 3 patients who developed nausea and vomiting, 2 patients that were non-compliant with the study procedures and 3 patients developed severe OM.

The purpose of the Phase 2 study (NCT03234465) is to evaluate the efficacy, safety and tolerability 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 as measured by the duration, time to development, and overall incidence of OM (World Health Organization scale used) during the active treatment phase, beginning from the start of chemoradiation therapy until 2 weeks following its completion.

“We are pleased with the conclusions reached by the DSMB. Of particular interest was the

low number of study discontinuations due to the development of severe OM which resulted in patients seeking alternative treatments for their condition. We are also pleased to note that we believe the overall incidence of severe OM is less than would be anticipated in the general population. While recognizing the preliminary nature of this phase of the study, such a finding might well suggest mitigation of severe OM by AG013," said Alan Joslyn, Oragenics' President and Chief Executive Officer. "Given the clearance by the DSMB, we will proceed with patient enrollment for our AGO13 clinical trial, which we hope to accelerate by the addition of clinical sites in the U.S. and Europe. We expect to report top-line results of the completed phase 2 trial in late 2019."

"The DSMB's findings are completely in line with the safety and tolerability signals observed in patients receiving induction chemotherapy for head and neck cancer and reported in the Phase 1b trial and pave the way for completion of a robust Phase 2," said Dr. Stephen Sonis, an expert in the field and advisor to Oragenics. "The unique delivery platform by which AG013 delivers hTTF1 represents an innovative approach with the potential to favorably impact the incidence and course of this devastating side effect of radiation therapy for patients being treated for head and neck cancer."

AG013 is an ActoBiotics® therapeutic candidate formulated as a convenient oral rinsing solution and designed by our strategic collaboration partner ActoBio Therapeutics, Inc., a wholly owned subsidiary of Intrexon Corporation (NYSE: XON) to deliver the therapeutic molecule Trefoil Factor 1 to the mucosal tissues in the oral cavity. 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. AG013 received Fast Track designation from the U.S. Food and Drug Administration in November 2016.

Under an Exclusive Channel Collaboration Agreement with ActoBio Therapeutics, Inc., a wholly owned subsidiary of Intrexon Corporation, Oragenics has an exclusive, worldwide license, to develop and commercialize AG013 to treat OM in cancer patients.

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, please visit www.oragenics.com.

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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 Food and Drug Administration approval for future 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, any inability to maintain compliance with the NYSE American 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.

AG013 is a mouth rinse formulation of a food grade microbe Lactococcus lactis producing human Trefoil Factor 1(hTFF1). Approximately 200 patients will be enrolled in the study. An initial cohort of at least 10 patients that received AG013 is included in the data set used for this interim analysis.

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