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Oragenics Completes Enrollment for the Interim Analysis Cohort in 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, today announced that it has completed enrollment of the interim analysis cohort of 20 patients in its Phase 2 clinical trial of AG013 for the treatment of oral mucositis (OM).

“We are very excited to complete this enrollment milestone for our Phase 2 trial of AG013 for oral mucositis, one of the most common and debilitating complications of chemo-radiation therapies. With no approved convenient preventative treatment, oral mucositis represents a serious unmet need for cancer patients receiving treatment on an outpatient basis,” said Alan Joslyn, Oragenics’ President and Chief Executive Officer. “After we complete this treatment phase and evaluate the safety of the initial 20 patients enrolled in the trial, we intend on expanding the trial in the United States and Europe to complete study enrollment. We expect to report preliminary data on the initial 20 enrolled patients during the second quarter of 2018 with top-line results of the trial expected in 2019.”

The purpose of the Phase II study (NCT03234465) is to evaluate the efficacy, safety and tolerability of topically administered AG013 compared to placebo for reducing Oral Mucositis (OM) in patients undergoing chemoradiation for the treatment of head and neck cancer, as measured by the duration, time to development, and overall incidence of OM (WHO scale used) during the active treatment phase, beginning from the start of chemoradiation therapy (CRT) until 2 weeks following its completion.

The Phase II trial is a double-blind, placebo-controlled, 2-arm, multi-center trial in which subjects will be randomized in a 1:1 ratio to receive either placebo or AG013. AG013 is a mouth rinse formulation of Lactococcus lactis strain sAGX0085, deficient in the gene coding for thymidylate synthase and producing human TFF1 (Trefoil Factor 1). Approximately 200 subjects will be enrolled in the study. An initial cohort of 10 patients that received AG013 is included in the 20 patients enrolled to date.

Safety will be evaluated on the basis of treatment-emergent AEs (TEAEs), vital signs, weight, physical examinations, clinical laboratory assessments and the presence of AG013-sAGX0085 in whole blood. Tolerability (taste, consistency and smell) will be collected from the patient diary.

In a Phase 1B study the efficacy analysis suggested a 35% reduction in percentage of days with UOM in AG013-subjects versus placebo. All placebo subjects experienced 2 days of

UOM, whereas 29% of AG013 subjects had UOM for 0 or 1 day. AG013 use resulted in fewer unscheduled office and emergency room visits. No differences were noted in mouth and throat soreness, opioid use, or gastrostomy tube placement.

In terms of safety and dosing, Oral live AG013 bacterial and hTFF1 levels in saliva and oral mucosa were equivalent among treatment groups. The most frequently occurring adverse events were nausea, oral pain, fatigue, diarrhea, and mucosal inflammation. Only 12% (3 of 25 adverse events), mainly nausea, were attributed to the investigational medicinal product: AG013 or placebo. Importantly, AG013 bacteria were not detected in blood.

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 (FDA) 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, www.oragenics.com

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Oragenics, Inc.
Corporate:
Michael Sullivan, 813-286-7900
Chief Financial Officer
msullivan@oragenics.com
or
Investor/Media Relations
The Ruth Group
Tram Bui, 646-536-7035
tbui@theruthgroup.com

Source: Oragenics, Inc.