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Oragenics, Inc. Announces Enrollment of 60th Patient in Clinical Trial

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 announces the enrollment of the 60th patient in its Phase 2 double blind, placebo controlled clinical trial of AG013 ([NCT03234465](https://clinicaltrials.gov/ct2/show/study/NCT03234465)).

AG013 is an oral mouth rinse composed of a recombinant *Lactococcus lactis* bacteria strain that contains the coding sequence for human trefoil family factor 1 (hTFF1), which is continually secreted by the bacteria. The trefoil factor family (TFF) is a family of three different peptides secreted by epithelial cells of the gastrointestinal tract in response to injury ([Hoffman, 2004](#)). Their presence has been implicated in reducing chemotherapy- and radiation-induced injury, both in preclinical studies ([Beck et al., 2004](#)) and in clinical trials ([Peterson et al., 2009](#)).

“We are encouraged and pleased to have made this important intermediate progress. The number of patients interested in participating in the clinical trial highlights the need for new treatment options for prevention of severe oral mucositis in this patient population,” said Alan Joslyn, CEO of Oragenics, Inc. “While we are confident in the measures we have taken to potentially expedite the pace of patient enrollment in future periods and we remain optimistic about such enrollment rates, given the pace of patient enrollment to date, we now anticipate that the top-line data readout of the AG013 study will likely occur in early 2020.”

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.

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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