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## Intrexon and Oragenics Expand Collaboration to Pursue Development of Biotherapeutics for the Oral Cavity

*Companies to Progress ActoBiotic™ AG013 for Treatment of Oral Mucositis Oragenics Now A Clinical Stage Company*

GERMANTOWN, Md. & TAMPA, Fla.-- [Intrexon Corporation](#) (NYSE:XON), a leader in synthetic biology, and [Oragenics](#) (NYSE MKT:OGEN), today announced a new Exclusive Channel Collaboration (ECC) to pursue development of biotherapeutics for oral mucositis (OM) and other diseases and conditions of the oral cavity, throat, and esophagus, including clinical advancement of the ActoBiotic™ AG013 for the treatment of OM. OM results in the painful inflammation and ulceration of the membranes lining the oral cavity, throat, and esophagus and is among the most frequently reported adverse events associated with cancer therapy affecting up to 500,000 patients annually. At present there is no drug approved to prevent the condition broadly and therapies are primarily palliative, alleviating symptoms without addressing the underlying pathology, resulting in a significant unmet medical need.

"We are eager to advance therapeutic programs through the established clinical foundations of the ActoBiotics™ platform, and moving forward in the clinic with AG013 is a natural fit for our focus on the treatment of oral cavity diseases with innovative biopharmaceuticals," said Frederick Telling, Ph.D., Chairman of the Board of Oragenics. "Work continues under our current collaboration with Intrexon centered on the development of a novel class of antibiotics known as lantibiotics, and we are excited to build on this relationship in the field of oral health to realize the promise of microbial approaches in the generation of efficacious new medicines."

"I am pleased that this new collaboration provides an opportunity for continued development of AG013 as an intervention for oral mucositis," said Stephen T. Sonis, DMD, DMSc, Senior Surgeon, Divisions of Oral Medicine, Brigham and Women's Hospital and the Dana-Farber Cancer Institute. "AG013's successful attenuation of chemotherapy-induced oral mucositis in the Phase 1B trial suggests that this innovative delivery platform may offer a new approach to the treatment of this important unmet clinical need."

Through the molecular engineering of food-grade microbes (*Lactococcus lactis*), biologically-contained ActoBiotics™ allow for *in situ* expression and secretion of novel biotherapeutic proteins and peptides. AG013 is formulated as a convenient oral rinsing solution and designed to deliver the therapeutic molecule Trefoil Factor 1 (TFF1) to the mucosal tissues in the oral cavity. TFFs are a class of peptides that are involved in protection of the

gastrointestinal tissues against mucosal damage and have an important role in subsequent repair.

A phase 1B clinical trial with AG013 in 25 cancer patients with OM across 5 cancer referral centers showed that AG013 was safe and well tolerated. Data published in the journal [Cancer](#) showed a 35% reduction of the duration of ulcerative OM in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of the patients treated with AG013 were full responders while all placebo-treated patients developed ulcerative OM. Additionally, a phase 1 pharmacokinetic (PK) study in 10 healthy volunteers showed that live AG013 bacteria adhere to the buccal mucosa and actively secrete protein locally, resulting in homogeneous exposure to the entire mucosal surface up to 24 hours after administration of a rinse. AG013 has already been granted Orphan Drug status in the European Union and has potential eligibility for Biologic License Application exclusivity as well as Fast Track designation with the United States Food and Drug Administration.

Under the terms of the agreement, Oragenics will have access to Intrexon's technologies and expertise to develop products for the treatment of oral mucositis or products containing genetically modified *Lactococcus lactis* expressing trefoil factors in the oral cavity, throat, and esophagus for a technology access fee and will reimburse Intrexon for the research and development costs. The agreement also provides for commercial and regulatory milestone payments to Intrexon, as well as a low double-digit percentage royalty based on the net sales from collaboration products.

“AG013 represents a promising product from a truly innovative platform for the prevention of oral mucositis in cancer patients,” commented Gregory Frost, Ph.D., Senior Vice President and Head of Intrexon’s Health Sector. “We are very pleased with the expanded collaboration with Oragenics, especially given their unique experience in the field of oral health using novel approaches. This ECC will further the clinical development of AG013 in the hope of providing cancer patients with a much needed adjunctive therapy for oral mucositis, a challenging side effect that can become a treatment-limiting toxicity for effective cancer therapy.”

### **About Intrexon Corporation**

Intrexon Corporation (NYSE:XON) is Powering the Bioindustrial Revolution with Better DNA™ to create biologically-based products that improve the quality of life and the health of the planet. The Company’s integrated technology suite provides its partners across diverse markets with industrial-scale design and development of complex biological systems delivering unprecedented control, quality, function, and performance of living cells. We call our synthetic biology approach Better DNA®, and we invite you to discover more at [www.dna.com](http://www.dna.com).

### **About Oragenics, Inc.**

Oragenics, Inc. is focused on becoming the world leader in novel antibiotics against infectious disease and probiotics for oral health in humans and pets. Oragenics, Inc. has previously established two exclusive worldwide channel collaborations with Intrexon Corporation Inc. (XON), a synthetic biology company. The collaborations will allow Oragenics access to Intrexon's proprietary technologies with the idea of accelerating the development of much needed new antibiotics that will work against resistant strains of

bacteria and new therapeutic probiotics designed to alleviate symptoms from oral diseases. Oragenics also develops, markets and sells proprietary OTC probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora both in the United States and through the use of distributors in locations outside of the United States.

## **Trademarks**

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## **Safe Harbor Statement**

Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon our current expectations and projections about future events and generally relate to our plans, objectives and expectations for the development of our business. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties and actual future results may be materially different from the plans, objectives and expectations expressed in this press release.

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