

## **NEWS**

### **FOR IMMEDIATE RELEASE:**

### **The GI Company Reports Significant Reduction in Occurrence of Oral Mucositis in Phase II Study; Abstract Posted Online at ASCO.org**

#### ***Oral Spray rhITF Formulation for Oral Mucositis is Safe, Well Tolerated and Effective when Dosed to Chemotherapy Patients***

**Framingham, MA – May 16, 2008** – The GI Company, Inc., a privately held developer of gastrointestinal therapeutics, today reported that the *American Society of Clinical Oncology* (ASCO) published an abstract containing a compelling data summary from a Phase II clinical study designed to evaluate the safety and efficacy of the company's lead clinical compound, Intestinal Trefoil Factor (rhITF). The GI Company's study abstract (ID: 9514 / 2006 – ITF – 009) is titled, *Prophylaxis of recurrent chemotherapy-induced oral mucositis: A Phase II multicenter, randomized, placebo-controlled trial of recombinant human Intestinal Trefoil Factor (rhITF)*.

Top-line data from this Phase II safety and efficacy study (2006 – ITF – 009) of rhITF administered to colorectal cancer patients at high risk of developing oral mucositis (OM) due to chemotherapy, revealed a statistically significant effect ( $p < 0.001$ ) on the prevention of grade 2 oral mucositis compared to placebo. The data also show rhITF oral spray to be safe, well tolerated and effective. The data confirm that prophylactic use of rhITF leads to a marked reduction in the occurrence of chemotherapy-induced oral mucositis in patients at high risk of developing oral lesions.

Nicholas Barker, Ph.D., President and Chief Executive Officer of The GI Company, commented on the study, "Oral mucositis is a debilitating disorder with no approved preventative measures. Our Phase II rhITF data show a highly statistically significant reduction in the incidence of oral mucositis. We look forward to presenting the full paper for peer review at ASCO."

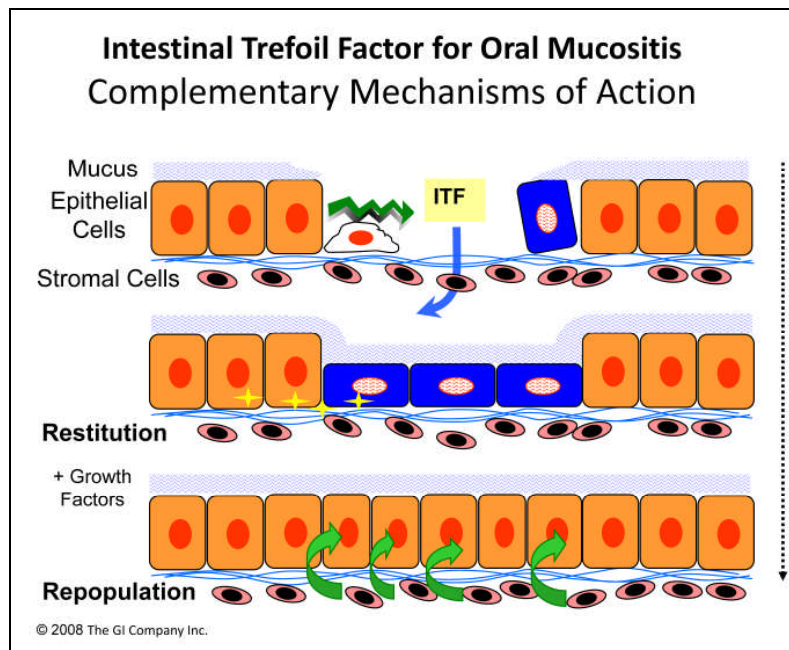
The oral presentation of these Phase II data, with full details from the study, will be presented by Dr. Nicholas Barker at the *ASCO 2008 Annual Meeting*. Dr. Barker's presentation is scheduled for Monday, June 2, 2008 from 3:30 PM - 3:45 PM in room S100a at McCormick Place, Chicago, Illinois.

All ASCO abstracts, including abstract ID: 9514 / 2006 – ITF – 009, were publicly posted on [www.ASCO.org](http://www.ASCO.org) on Thursday, May 15 at 9:00 PM (EDT).

Douglas E. Peterson, DMD, Ph.D., co-author and a recognized thought leader in the field of oral and gastrointestinal mucosal injury, commented on the study, “The side effects of chemotherapy are debilitating and often result in oral and esophageal ulcers, severe pain, edema, dryness of the mouth and the inability to swallow. These cancer patients and their families are suffering enough, and a therapeutic intervention for this terrible chemotherapy side effect has been a long time coming. It appears that rhITF may be able to reduce this incidence of mucositis, thereby providing therapeutic relief to this underserved patient population.”



*The GI Company's proprietary, directional, oral-delivery system is designed to deliver rhITF directly to the oral cavity.*



*The GI Company's rhITF mucositis therapy is being developed to alleviate damage to the soft tissues of the oral cavity by providing rhITF to the cells of the mouth and throat, thereby preventing oral mucositis.*

The GI Company's lead Phase II clinical compound, Intestinal Trefoil Factor (rhITF), is in development for oral mucositis, a common, debilitating complication resulting from high-dose chemotherapy and / or radiotherapy. The company also has clinical rhITF programs in a variety of conditions such as erosive gastritis (NSAID induced), ulcerative colitis and corneal wound healing.

The GI Company has retained Burrill & Company to assist in the selection of a transaction partner for its clinical programs.

### **About Intestinal Trefoil Factor (ITF)**

Intestinal Trefoil Factor (ITF) is found primarily on mucosal surfaces throughout the gastrointestinal tract, including the mouth, esophagus and intestines, as well as in other tissues such as the eye and lungs. The protein is known to promote mucosal restitution and repair and is therefore being developed as a therapeutic. rhITF mucositis therapy is designed to alleviate damage to the soft tissues of the oral cavity by providing rhITF to the cells of the mouth and throat using a proprietary buccal (oral) delivery system. This therapeutic target is backed by proven biology and compelling efficacy data on ITF in numerous *in vivo* models of mucosal damage.

### **About Oral Mucositis**

Oral mucositis, also called stomatitis, is a common, serious complication resulting from high-dose chemotherapy and / or radiotherapy. These cytotoxic therapies are used to kill cancer cells, but they also indiscriminately kill other fast-growing cells such as those lining the inside of the mouth and throat. Oral mucositis is an inflammation of the mucosa of the mouth which ranges from redness to severe ulcerations on the inner cheek, tongue and lips. These debilitating oral sores further diminish quality of life by preventing patients from eating, drinking, or talking for weeks at a time. These conditions can reappear after every course of treatment. In addition to extremely painful open oral sores, patients with oral mucositis typically have diminished immunity resulting from chemotherapy and / or radiotherapy and are prone to serious life-threatening opportunistic infections. Currently, there is no effective treatment approved to prevent oral mucositis or shorten its duration. This condition can affect as many as 80 percent of bone marrow / blood stem cell transplant patients and 40 percent of chemotherapy / radiotherapy patients. This market represents a \$1B annual market opportunity in the U.S. alone.

## **About ASCO**

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who care for people with cancer. With more than 25,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. For ASCO information and resources, visit [www.asco.org/presscenter](http://www.asco.org/presscenter). Patient-oriented cancer information is available at [www.plwc.org](http://www.plwc.org).

## **About The GI Company, Inc.**

The GI Company is a clinical-stage biotechnology company highly specialized at developing drugs to treat gastrointestinal and related diseases. The company's lead clinical candidate is Intestinal Trefoil Factor (rhITF) which is being developed for the treatment of oral mucositis. The GI Company also has pre-clinical development projects in Enteritis/Proctitis, Inflammatory Bowel Disease, Erosive Gastroesophageal Reflux Disease, Peptic Ulcer disease and gastrointestinal motility disorders. The company is funded through a private equity financing consortium and has raised over \$20M to date. For more information, please visit [www.thegicompany.com](http://www.thegicompany.com).

# # #

### **Contact:**

Bryan P. Murphy  
LaVoie Group  
978.745.4200 x 105  
[bmurphy@lavoiegroup.com](mailto:bmurphy@lavoiegroup.com)

Tim Allison  
LaVoie Group  
978.745.4200 x 102  
[tallison@lavoiegroup.com](mailto:tallison@lavoiegroup.com)