

NEWS

FOR IMMEDIATE RELEASE:

The GI Company Reports Significant Reduction in Occurrence of Oral Mucositis in Phase II Study Presented at ASCO

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

Framingham, MA, and Chicago, IL – June 2, 2008 – The GI Company, Inc., a privately held developer of gastrointestinal therapeutics, today presented final results of a Phase II clinical study designed to evaluate the safety and efficacy of the company's lead drug, Intestinal Trefoil Factor (rhITF) at the *American Society of Clinical Oncology (ASCO) 2008 Annual Meeting*. The GI Company's study abstract (ID: 9514 / 2006 – ITF – 009), first published online at ASCO's website on May 15, is titled, *Prophylaxis of recurrent chemotherapy-induced oral mucositis: A Phase II multicenter, randomized, placebo-controlled trial of recombinant human Intestinal Trefoil Factor (rhITF)*.

Today at the *ASCO 2008 Annual Meeting*, Nicholas Barker, Ph.D., presented full details of the Phase II clinical study. Study 2006 – ITF – 009 was designed to evaluate the safety and efficacy of rhITF as an oral spray to prevent oral mucositis. rhITF treatment was administered topically to the oral cavity of colorectal cancer patients at high risk of developing oral mucositis (OM) due to chemotherapy. The data show that prophylactic use of rhITF leads to a marked, statistically significant reduction in the occurrence of chemotherapy-induced oral mucositis in this patient population.

This Phase II study met its primary efficacy endpoint as measured by a statistically significant reduction ($p < 0.001$) in the proportion of patients developing World Health Organization Scale (WHO Scale) grade ≥ 2 oral mucositis (low dose arm 81% / high dose arm 75% decrease) compared to placebo. The study also met its secondary endpoints in mean/median peak oral mucositis scores (WHO Scale and Oral Mucositis Assessment Scale: OMAS). rhITF oral spray was also shown to be safe and well tolerated with no serious adverse events and very few mild-to-moderate adverse events reported.

There were also some statistical differences in the patient diary parameters of placebo patients, most notably increased occurrences of oral discoloration, mouth soreness and overall preference for semi-solid food.

Nicholas Barker, Ph.D., President and Chief Executive Officer of The GI Company, commented on the study, “It is our hope to make a difference in the quality of life of chemotherapy patients. There are so many people that suffer from this terrible chemotherapy side effect and it is gratifying to have demonstrated striking efficacy in a clinical trial that indicates rhITF oral spray may provide therapeutic relief to this needy patient population.”

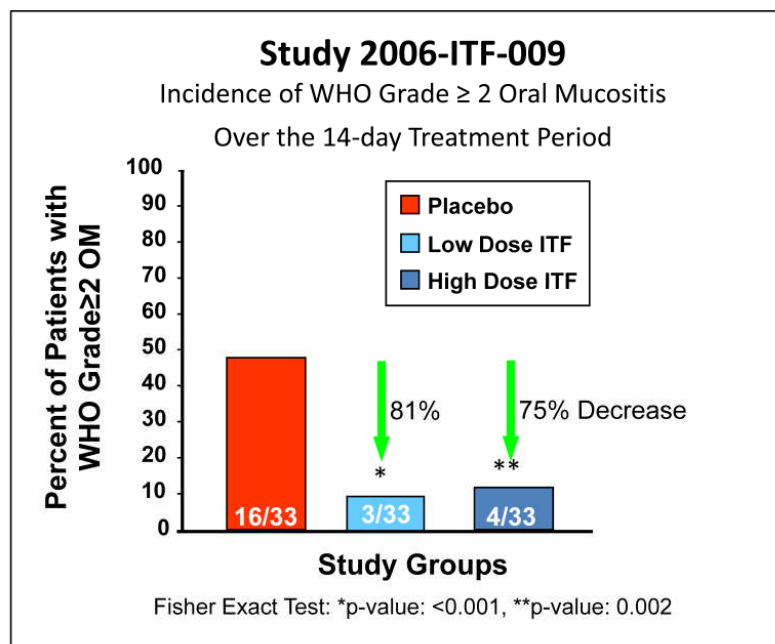
Dr. Barker continued, “The GI Company’s lead clinical compound, rhITF, is now well positioned to find a transaction partner to take this important new oral mucositis therapeutic into Phase III clinical development and expedite its commercialization.”

2006 – ITF – 009 Study Design

Stage I to IV colorectal cancer patients (N=99) that had experienced symptomatic OM (WHO grade ≥ 2) in the first cycle of chemotherapy were enrolled. After spontaneous resolution of first cycle mucositis, the patients were randomized at the start of their second cycle of chemotherapy into three groups (N=33/group) and treated with either placebo, rhITF 10 mg/ml (low dose) or rhITF 80 mg/ml (high dose) by oral spray (300 μ l, 8 times/day) for 14 consecutive days. Patients were assessed on days 1, 3, 5, 7, 10, 12, 14 and 21 \pm 2 for WHO and OMAS grades of OM, and treatment-related effects.

Frequency of WHO grade ≥ 2 oral mucositis in the placebo, low-dose rhITF and high-dose rhITF groups was 48.5% (16/33), 9.1% (3/33) and 12.1% (4/33), respectively, reflecting a reduction of 81% and 75% respectively (for either low or high dose) versus placebo, which is highly statistically significant ($p < 0.001$).

Assessment of area under the curve relative to OM / incidence and severity revealed a comparable treatment effect of rhITF versus placebo (WHO scores, $p < 0.001$).

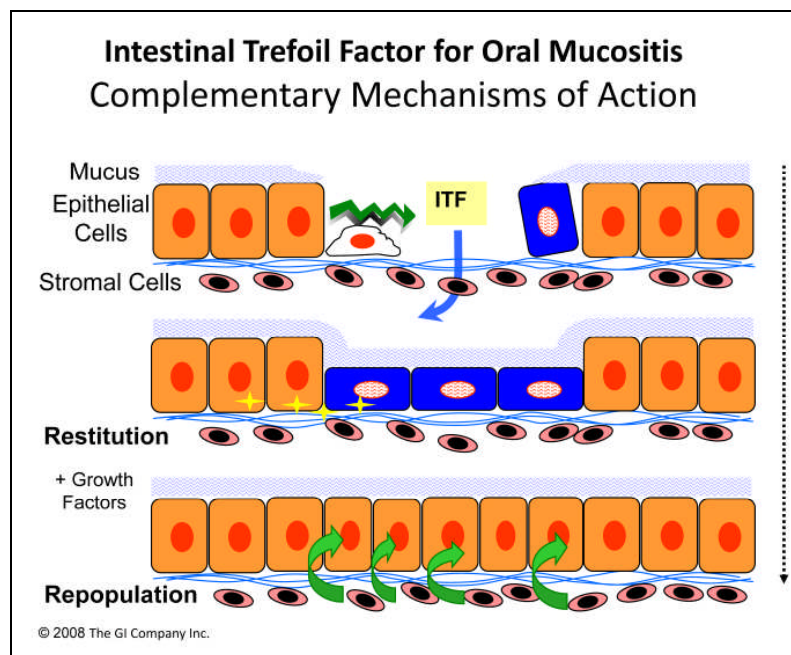


The GI Company's lead Phase II clinical compound, Intestinal Trefoil Factor (rhITF), is in development for oral mucositis, a common, debilitating complication resulting from high-dose chemotherapy and / or radiotherapy. The company also has clinical rhITF programs in a variety of conditions such as erosive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



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.

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. Patient-oriented cancer information is available at 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.

Contact:

Bryan P. Murphy
LaVoie Group
978.745.4200 x 105
bmurphy@lavoiegroup.com

Tim Allison
LaVoie Group
978.745.4200 x 102
tallison@lavoiegroup.com