

NEWS

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The GI Company Reports Additional Phase II Clinical Data of Intestinal Trefoil Factor (rhITF) Oral Spray for Oral Mucositis

OMAS Scoring Confirms rhITF Demonstrates Statistically Significant Prophylaxis for Oral Mucositis

Framingham, MA and Houston, Texas – June 30, 2008 – At the *Multinational Association of Supportive Care in Cancer and the International Society of Oral Oncology's 2008 International Symposium on Supportive Care in Cancer (MASCC / ISOO)* held last week in Houston, Texas, The GI Company reported secondary endpoints relating to Oral Mucositis Assessment Scale (OMAS) scores from the Company's Phase II clinical study, designed to evaluate the safety and efficacy of its lead clinical compound, Intestinal Trefoil Factor (rhITF) Oral Spray, in development for oral mucositis. 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 / radiation therapy patients. In addition, Phase I results detailing dosing and kinetic properties in the oral cavity were also reported. rhITF is an oral spray in development for the prevention of chemotherapy-induced oral mucositis.

The Phase II study was featured in the poster presentation titled, "*Recombinant human intestinal trefoil factor (rhITF) oral spray for prophylaxis of chemotherapy-induced oral mucositis.*" The data presented demonstrated that in addition to meeting the primary World Health Organization Scale endpoint (WHO Scale combines objective changes with functional outcomes to arrive at a score), the study also met its secondary endpoint OMAS score. The OMAS and WHO score systems are complementary; OMAS is a novel, objective, validated quantification tool to enable physicians to quantitate mucosal tissue damage and has been developed by a multidisciplinary team to assess the utility of new agents for oral mucositis in clinical trials (Sonis, Cancer, 1999).

Presenting at the symposium was Douglas E. Peterson, DMD, Ph.D., a co-author and a recognized thought leader in the field of oral and gastrointestinal mucosal injury. Dr. Peterson commented, "The side effects of chemotherapy are debilitating and often result in oral and esophageal ulcers, severe mouth pain, edema, and the inability to swallow. rhITF represents an important advance in the management of patients who may experience this potentially devastating and treatment limiting condition. The data strongly indicate that prophylactic use of rhITF can lead to a marked reduction in the occurrence of chemotherapy-induced oral mucositis in patients at high risk of otherwise developing the toxicity."

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Mean OMAS scores were consistently and significantly lower in the low and high dose rhITF treatment arms compared to placebo over days 7 to 14, post-chemotherapy ($p < 0.001$ to 0.013 ; D7-D14 [ANOVA]) and showed significant reduction in the frequency of grade ≥ 2 oral mucositis in 99 colorectal cancer patients at high risk for developing chemotherapy-induced oral mucositis.

The data on the mean total OMAS scores and the area under the curve (OMAS score) provided strong concurrence with the WHO Scale primary endpoint. Patients received 10 or 80 mg/mL of rhITF via oral spray for 14 days in their second chemotherapy cycle.

Nicholas Barker, Ph.D., President and Chief Executive Officer of The GI Company, commented, "ITF Oral Spray demonstrated highly statistically significant reductions in the incidence of oral mucositis, and it was also shown to be safe and well tolerated. These OMAS results are consistent with, and reinforce, the data reported at the *American Society of Clinical Oncology (ASCO)* on June 2, 2008 and provide additional support to move this compound forward into next-stage clinical trials. ITF therefore represents a novel, safe, effective and convenient treatment option, in an area of high unmet medical need."

In a podium presentation at ASCO on June 2, Dr. Barker reported primary endpoint data from the Company's Phase II study which demonstrated a statistically significant reduction ($p = < 0.001$) in the proportion of patients developing WHO Scale grade ≥ 2 oral mucositis (low dose rhITF arm 81 percent / high dose rhITF arm 75 percent decrease) compared to placebo.

The objective of the Phase I study, also reported today, was to study dosing schedule and kinetic properties of the rhITF Oral Spray for use in patients with oral mucositis lesions. Results of this Phase I, randomized, double blind, placebo-controlled study examining the kinetic profile of a single dose of rhITF sprayed onto the oral mucosa of 10 healthy volunteers (7 active treatment group / 3 placebo group) provided valuable information for guiding future clinical trials. The study revealed that the application of a single 12 milligram dose of rhITF Oral Spray increased ITF immunoreactivity on the adherent mucus in the oral cavity by >500 fold with a residence half-life of 12.71 ± 6.65 minutes. rhITF was detected on the oral mucosa at least 60 minutes post-dose.

The GI Company's lead Phase II clinical candidate, Intestinal Trefoil Factor (rhITF), is a recombinant protein in development for the treatment of oral mucositis, a common, debilitating complication resulting from high-dose chemotherapy and / or radiation therapy. The GI Company has retained Burrill & Company to assist in the selection of a development partner for its clinical programs.

About Intestinal Trefoil Factor

Intestinal Trefoil Factor is an endogenous protein found primarily on mucosal surfaces throughout the gastrointestinal tract, including the mouth, esophagus and intestines, as well as in other tissues such as the eyes and lungs. The protein is known to promote mucosal restitution and repair. rhITF mucositis therapy is intended to alleviate damage to the soft tissues of the oral cavity by providing therapeutic concentrations of recombinant human ITF to the cells of the mouth and throat using a proprietary buccal (oral) delivery system. This treatment modality 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 and serious complication resulting from high-dose chemotherapy and / or radiation therapy. These cytoreductive therapies aimed at killing cancer cells can also indiscriminately destroy other fast-growing cells such as the lining 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 radiation therapy and are prone to serious life-threatening opportunistic infections. This market represents a \$1B annual market opportunity in the U.S. alone.

About MASCC

The Multinational Association of Supportive Care in Cancer (MASCC) is an international, multidisciplinary organization with members representing over 60 countries and five continents. Founded in 1990, MASCC is dedicated to research and education in all aspects of supportive care for patients with cancer, regardless of the stage of their disease. In 1998 MASCC joined forces with the International Society of Oral Oncology (ISOO), an organization that addresses the management of complications arising in oral tissues secondary to cancer and its treatment. For more information, please visit <http://www.mascc.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 (ITF) 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, as well as clinical programs in erosive gastritis (NSAID induced), ulcerative colitis and corneal wound healing. 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.

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