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VSL#3[®] Probiotic Shown Effective in Dietary Management of Children with Irritable Bowel Syndrome

GAITHERSBURG, MD – August 16, 2010 – New data show that VSL#3, a high-potency probiotic medical food, provides effective dietary management of children affected with irritable bowel syndrome (IBS).

Until recently, little has been done to understand the role of probiotics in **the dietary management of children with IBS**. Now, data is available showing VSL#3 as an option for children suffering from this disorder. These data were published in the July issue of the *Journal of Pediatric Gastroenterology and Nutrition*.

“There is evidence that some probiotics, such as VSL#3, have a beneficial role in the dietary management of children and teenagers suffering with IBS,” said Stefano Guandalini, MD, Professor and Chief of the Section of Pediatric Gastroenterology, Hepatology and Nutrition at the University of Chicago. “This has the potential to make a real difference for kids who suffer from pain, bloating and discomfort of IBS.”

This investigation was a randomized, double-blind, placebo-controlled, crossover trial conducted in five pediatric tertiary care centers. Patients eligible for enrollment were male and female children in the age range of 4 to 18 years, with an IBS diagnosis. A total of 59 children completed the study. Although placebo was beneficial in some of the parameters and in as many as half of the patients, VSL#3 was significantly superior to placebo in reaching the primary (relief of symptoms) and most secondary endpoints (abdominal pain/discomfort, abdominal bloating/gassiness and family assessment of life disruption).

About Irritable Bowel Syndrome (IBS)

IBS is a common problem in pediatrics, for which no cure is available. This disorder is characterized most commonly by cramping, abdominal pain, bloating, constipation, and diarrhea. IBS causes a great deal of discomfort and distress, but it does not permanently harm the intestines and does not lead to a serious disease, such as cancer. IBS is common in people of all ages, including children. About 14 percent of high school students and 6 percent of middle school students report IBS-like symptoms.

About VSL#3[®]

VSL#3[®] is a high-potency probiotic medical food, containing several different strains of beneficial bacteria that were specially selected to produce an optimal composition of beneficial bacteria. VSL#3 colonizes the gastrointestinal (GI) tract with optimal quantities and types of probiotic (“good”) bacteria. Using this high concentration of several different strains of specially selected beneficial bacteria, VSL#3 provides an optimal composition of good bacteria, enhancing

the health of the GI tract and aiding in dietary management of IBS. Each packet of VSL#3 contains 450 billion CFU.

VSL#3[®] is a registered trademark of VSL Pharmaceuticals Inc. VSL#3[®] is a product that has been licensed from VSL Pharmaceuticals Inc. to Sigma-Tau Pharmaceuticals, Inc. for the U.S. territory. For more information, visit www.vsl3.com.

About Sigma-Tau Pharmaceuticals, Inc.

Sigma-Tau Pharmaceuticals, Inc. is a U.S. based, wholly owned subsidiary of the sigma-tau Group, and is dedicated solely to the global development and commercialization of medicines for patients with rare diseases. Sigma-Tau Pharmaceuticals, Inc. is based in Gaithersburg, Maryland. Since 1989, the company's products have been focused on rare diseases, kidney disease, and cancer. For more information about the company, visit www.sigmatau.com.

About VSL Pharmaceuticals Inc.

VSL Pharmaceuticals Inc. is a privately owned biotechnology company focusing on the research and development of innovative solutions derived from the concept of probiotics through numerous experimental and clinical researches. VSL#3[®], its first marketed product, has been extensively studied in almost 100 original publications and is currently commercialized in 15 countries worldwide for the dietary management of conditions such as IBD (Inflammatory Bowel Disease) and IBS (Irritable Bowel Syndrome) for adult and children.

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