Spherix Announces Positive Phase 2 Study Results

Preliminary Data Demonstrates Reduction of HbA1c Levels With Doses an Order of Magnitude Lower than the Dose Used in the Current Phase 3 Trial

Bethesda, MD – June 24, 2009 - Spherix Incorporated (NASDAQ CM: SPEX), an innovator in biotechnology for diabetes therapy, and a provider of technical and regulatory consulting services to food, supplement, biotechnology and pharmaceutical companies, today announced positive preliminary results from a Phase 2 clinical trial of its novel compound, Naturlose® (D-tagatose), in the treatment and management of Type 2 diabetes. The Phase 2 trial is expected to be completed in early 2010.

In the ongoing single-blind study designed to establish the minimum dose of Naturlose capable of causing a beneficial effect, Naturlose is administered orally with meals, three times daily (TID) at three different doses: 2.5, 5.0, and 7.5 g. The comparator is the 2.5 g dose. The primary endpoint for the study is reduction in HbA1c after 6 months on the drug. After 6 months on drug, the patients in the 7.5 g group experienced an average reduction of 0.3% in HbA1c from the HbA1c of the 2.5 g group. At that same 6-month point, the 5.0 g group averaged a reduction in HbA1c of 0.05% from the 2.5 g group. Naturlose appears to begin showing an effect on HbA1c within the range of doses selected for this minimum-dose study. The ongoing Phase 3 double-blinded study of efficacy is being conducted at a 15 g dose (TID), and is powered to detect a 0.5% reduction in HbA1c.

Over the course of the Phase 2 trial, Naturlose also decreased the average serum triglycerides of the patients by -59 mg/dl by the end of the first month on therapy, a decrease from baseline that remained at -41 mg/dl by the end of the 6 months of the trial. Naturlose also decreased serum LDL by an average -13 mg/dl by the end of the first month on therapy, while serum HDL was essentially unchanged (+0.9 mg/dl). The LDL:HDL ratio was improved for two of the three dose groups by an average of 0.3.

“The results of this ongoing Phase 2 study are encouraging and reaffirm our belief that Naturlose may be a valuable treatment option for patients with Type 2 diabetes,” said Dr. Claire Kruger, CEO of Spherix. “Naturlose, administered at three separate low doses, proved to be effective for at least 6 months in reducing HbA1c, a key indicator of Type 2 diabetes that monitors glycated hemoglobin in the blood. These data, combined with the fact that Naturlose is a naturally occurring compound with no known contraindications to current Type 2 diabetes treatments, continues to lead us to believe that there will likely be a place for Naturlose in the treatment regime as either a stand-alone or an adjunct therapy. In addition, the effect on serum lipoproteins may lead to a role for Naturlose in the treatment of atherosclerosis and the metabolic syndrome.”

Phase 2 Study Design

This phase 2 single-blind, prospective, randomized, multicenter study evaluated the minimum oral dose of Naturlose capable of causing a beneficial effect on HbA1c, and the safety of such doses. Naturlose was administered orally with meals (TID) at three different doses, 2.5, 5.0, and 7.5 g. Patients were required to pass specific inclusion criteria at screening and at baseline, including an HbA1c level at screening and baseline between 6.6% and 9.0%. The baseline visit followed an 8-week run-in period in which patients were instructed to follow a weight-maintaining diet and a daily exercise program under the supervision of the investigator. The run-in period was designed to compensate for the effect of diet and exercise on the estimated effectiveness of the drug. The treatment duration was six months and 38 patients have been randomized to one of the three doses to date. Patients with a current or recent history (within the prior 3 months) of treatment with any oral or injectable anti-diabetic treatment were excluded from the study, as well as any having one or more episodes of severe hypoglycemia within six months prior to entry into the study, or currently diagnosed as having hypoglycemia unawareness.

In this trial, Naturlose was safe and well tolerated. Low rates of treatment-related adverse events were noted at all doses. The most common adverse events reported in the trial were mild and gastrointestinal in nature.
Prior Studies with Naturlose

A recent controlled animal study demonstrated that, in comparison to sucrose, equivalent substitution of Naturlose as dietary carbohydrate results in less obesity, hyperglycemia, hyperlipidemia, and atherosclerosis (Police SB, Harris JC, Lodder RA, Cassis LA. Effect of diets containing sucrose vs. D-tagatose in hypercholesterolemic mice. *Obesity*. 2009 Feb;17(2):269-75.). A novel finding in this study was that atherosclerotic lesions detected in TAG-fed mice were composed of increased collagen, indicative of a more stable plaque phenotype. The results suggest that, in addition to minimizing the extent of atherosclerosis from carbohydrate consumption, a diet enriched in tagatose may favor a more stable plaque phenotype less likely to cause stroke or myocardial infarction.

Prior Clinical Trials with Naturlose

Eight healthy individuals and eight individuals with type 2 diabetes underwent separate 3-hour oral glucose and tagatose tolerance tests. The subjects were also given 75 g of tagatose followed 30 minutes later by 75 g of glucose. Between test days, participants received 10 g of tagatose per day. Ingestion of the tagatose load (75 g) caused no increase in plasma insulin or glucose concentrations in either healthy or diabetic individuals. (Donner TW, Wilber JF, Ostrowski D. D-Tagatose, a novel hexose: Acute effects on carbohydrate tolerance in subjects with and without type 2 diabetes. *Diabetes Obesity Metab* 1999 I 5 285-291)

A dose and time-of-administration study was conducted to verify the dosing plan to be used in the phase 3 trial. It was a randomized, open-label, 3 x 3 factorial design for an instant mashed potato load, and a 2 x 3 factorial design for a glucose load in which each subject participated in 11 separate 2-h meal or glucose tolerance tests. A total of 33 non-diabetic, healthy subjects (18 males and 15 females) aged 18–44 years who had satisfied the screening evaluation were enrolled into the study. Treatment with tagatose, whether it was at a dose of 10 g or 15 g, whether it was taken with or before the meal or glucose load, blunted the rise of plasma glucose (Yongming Lu, Gilbert Levin, Thomas Donner. Tagatose, a New Anti-Diabetic and Obesity-Control Drug. *Diabetes, Obesity and Metabolism*. 10, 2008, 109–134.)

About Type 2 Diabetes

Type 2 diabetes mellitus (T2DM) is a disease that is characterized by elevated blood glucose in the context of insulin resistance and comparative insulin deficiency. While T2DM is often initially managed by increasing exercise in conjunction with dietary modification, medications are usually needed as the disease progresses. There are an estimated 23.6 million people in the U.S. (7.8% of the population) with diabetes, and 17.9 million cases have been diagnosed. Of the diagnosed diabetes cases, 90% are type 2. As T2DM prevalence rates doubled between 1990 and 2005, the CDC characterized the increase as an epidemic. Customarily considered a disease of adults, T2DM is increasingly being diagnosed in children in correlation to increasing juvenile obesity rates.

About Naturlose

Spherix holds patents on the use of Naturlose as a drug to treat diabetes. Naturlose is D-tagatose, which occurs naturally in small amounts in dairy products. It is a highly soluble white crystal or powder, can be produced with a physical bulk similar to ordinary table sugar, and is 92% as sweet. In the U.S., based on over 10 years of animal, human, and other relevant use and safety data, Naturlose was determined to be Generally Recognized As Safe (GRAS) for use in foods as regulated by the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. Naturlose has been approved as a "novel food ingredient" in the European Union (EU) without any restriction on usages. Nutraceutical or functional foods are foods with health-promoting or dietary management properties beyond the basic function of supplying nutrients and are a growing segment of the industry due to their increasing popularity with health-conscious consumers.

About Spherix

Spherix Incorporated was launched in 1967 as a scientific research company, under the name Biospherics Research. The company now leverages its scientific and technical expertise and experience through its two subsidiaries—Biospherics Incorporated and Spherix Consulting, Inc. Biospherics is currently running a Phase 3 clinical trial to study the use of Naturlose as a treatment for Type 2 diabetes. Its Spherix Consulting subsidiary provides scientific and strategic support for suppliers, manufacturers, distributors and retailers of conventional foods, biotechnology-derived foods, medical foods, infant formulas, food ingredients, dietary supplements, food contact substances, pharmaceuticals, medical devices, consumer products, and industrial chemicals and pesticides. For more information, please visit www.spherix.com.
Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of Naturlose, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our continuing efforts to develop Naturlose may be unsuccessful, our common stock could be delisted from the Nasdaq Capital Market, and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our current report on Form 8-K filed on October 10, 2007. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.