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## SPHERIX ANNOUNCES STATISTICALLY SIGNIFICANT RESULTS IN PHASE 3 STUDY WITH D-TAGATOSE IN TYPE 2 DIABETES

*Statistically Significant Reductions in HbA1c Achieved at 2, 6, and 10 Months;  
Reduction in HbA1c Increases Over Time*

**BETHESDA, MD (October 7, 2010)** – Spherix Incorporated (NASDAQ: SPEX), an innovator in biotechnology for therapy in diabetes, metabolic syndrome and atherosclerosis; and providers of technical and regulatory consulting services to food, supplement, biotechnology and pharmaceutical companies, today announced that its Phase 3 study of D-tagatose as a monotherapy in Type 2 diabetes showed a statistically significant ( $p < 0.05$ ) reduction in HbA1c levels of 0.4% at 10 months in relatively healthy people with diabetes (U.S. ITT LOCF,  $n=101$  and Global PP,  $n=92$ ).<sup>\*</sup> The reduction was even more pronounced among PP patients treated in the U.S., and the reduction in HbA1c generally increased over the 10 months patients were treated (see Table 1).

The NEET (Naturlose® Efficacy Evaluation Trial) data show that D-tagatose was more effective in the U.S. population than in the Indian population, as the PP patients in the U.S. who were treated with D-tagatose had a reduction in HbA1c of 0.4% at two months, 0.6% at six months and 1.1% at 10 months on therapy ( $p < 0.05$ ).

Patients in the study had a low average randomization HbA1c of 7.5% globally. An HbA1c level of 6% or below is considered normal. An 8% level is considered high. The American Diabetes Association recommends a goal of reducing HbA1c to 7% or below in people with diabetes.

“These are promising results and we are pleased with the significant drop in HbA1c levels among patients treated with D-tagatose. As a monotherapy in a patient population with mild disease, this achievement is even more compelling,” said Dr. Claire Kruger, Chief Executive Officer of Spherix. “We believe that further development in the Type 2 diabetes indication is merited, and we look forward to engaging a partner to continue this work.”

John Amatruda, M.D., a drug-development executive who was formerly Senior Vice President and Franchise Head, Diabetes and Obesity, at Merck Research Laboratories and is now an advisor to Spherix, summarized clinical trial expectations. According to Dr. Amatruda, “Decreases in HbA1c with drugs to treat Type 2 diabetes are dependent on the baseline HbA1c; the higher the baseline the greater the decrease (Bloomgarden et al, Diabetes Care, Volume 29 Number 9 September 2006). Generally, one would not expect large decreases in HbA1c if the mean HbA1c at randomization is 7.5%.”

Patients with HbA1c levels between 8.0% and 9.0% globally, which are at the high end of the inclusion criteria, showed 0.7% reduction on D-tagatose at 10 months of therapy (PP, not shown in table). This occurred in a subpopulation of patients using the drug per protocol, but was not with statistical significance ( $p=0.09$ ) due to the small number of patients ( $n=30$ ) with HbA1c values at those levels. “We are very encouraged by the response seen in patients with poorer control of blood sugar as measured by HbA1c in the NEET study,” stated Dr. Robert Lodder, President of Spherix.

Tolerability data are still being analyzed, but the number of patients with one or more treatment-emergent adverse events in the active group (163) was comparable to those reported in the placebo group (166). No serious adverse event was deemed to be treatment related. No episodes of hypoglycemia or pancreatitis were reported in NEET.

<sup>\*</sup> PP = Per-Protocol; ITT = Intent-to-Treat; LOCF = Last Observation Carried Forward

## **Next Steps**

Spherix intends to submit a detailed analysis of the Phase 3 data to a peer-reviewed medical journal after the complete study report is received later this year. Spherix will also post the final trial results on the public NIH ClinicalTrials.gov website as required by law. In addition, Spherix will begin discussions with pharmaceutical companies and participate in two upcoming industry meetings: BioPartnering Europe, October 11-12 in London; and the Windhover Therapy Area conference, November 3-4 in Boston.

## **Triglycerides**

Because of the small number of patients enrolled in the NEET diabetes trial with triglyceride levels of 200 to 500 mg/dl, and a lack of patients with triglyceride levels above 500 mg/dl, it was not possible to conduct statistical analyses on that secondary endpoint in the current trial. Dr. Lodder's previous research in an animal model of dietary-induced hyperlipidemia demonstrated an effect of D-tagatose on triglycerides, VLDL, LDL in blood, and on atherosclerosis in arterial walls. Animals consuming D-tagatose exhibited a statistically significant five- to six-fold reduction in triglycerides compared with animals consuming sucrose.

"We plan to continue with our stated goal of investigating the development of D-tagatose as a therapy for reduction of triglycerides," Dr. Lodder said.

## **NEET Trial Design**

NEET is a double-blind, placebo-controlled trial with 356 treatment-naïve patients randomized to receive 15 grams of D-tagatose three times daily with meals for a period of up to one year as an adjunct to diet and exercise, or a placebo three times daily with meals for up to one year as an adjunct to diet and exercise. Patients were treated for more than 10 months, and HbA1c levels were measured at two, six and 10 months after enrollment into the trial. The average HbA1c level at the time of entering the trial was 7.5%. The NEET inclusion criteria for HbA1c in patients were screening (visit 1) and randomization (visit 2) values between 6.6% and 9.0%.

A modified Intent-To-Treat (ITT) definition was used in NEET. The modified ITT population consisted of all randomized subjects who received at least one dose of their randomized treatment and had at least one post-treatment visit evaluating efficacy. The PP population consisted of all ITT subjects who had 80% compliance with medication for 75% of the dosing time points and had no major protocol violations. Last Observation Carried Forward (LOCF), a method in which the last results before a subject drops out of the trial are carried forward to the end of the trial, was used in the ITT population when data were missing due to circumstances such as loss to follow-up. The trial was conducted at 34 sites in the U.S. and 23 sites in India. The final patient numbers were 172 in the drug arm and 184 in the placebo arm (ITT), and 85 in the drug arm and 119 in the placebo arm (PP). A total of 102 patients were enrolled at U.S. sites, and 254 patients were enrolled at India sites. The trial was initially powered by design to detect a reduction in HbA1c of 0.5%, but the variance in HbA1c at each time point was smaller than the original design assumption, enabling a smaller change in HbA1c to be detected with statistical significance. Secondary endpoints included glucose measures, insulin measures, lipid profiles and changes in body weight.

**Table 1. Reduction in HbA1c Over Time**

Patient population	2 months	6 months	10 months
U.S. PP	-0.4* (n=51)	-0.6* (n=29)	-1.1* (n=20)
U.S. ITT LOCF	-0.3* (n=100)	-0.3* (n=101)	-0.4* (n=101)
India PP	-0.1 (n=150)	0.0 (n=117)	-0.2 (n=72)
India ITT LOCF	-0.2 (n=253)	-0.1 (n=254)	-0.2* (n=254)
Global PP	-0.2 (n=201)	-0.2* (n=146)	-0.4* (n=92)
Global ITT LOCF	-0.2* (n=353)	-0.2* (n=355)	-0.2* (n=355)
Global ITT (7.5<HbA1c<9.0)	-0.3 (n=175)	0.1 (n=134)	-0.5* (n=92)

PP = Per-Protocol; ITT = Intent-to-Treat; LOCF = Last Observation Carried Forward

\* p<0.05; all other figures do not have statistical significance

### 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 recently completed a Phase 3 clinical trial to study the use of D-tagatose 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](http://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 D-tagatose, 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 D-tagatose 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.

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