



Press Release

ProStrakan Group plc

Testosterone replacement study shows positive results in diabetic men from 2% testosterone gel

Galashiels, Scotland, 18 June, 2008 -- ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today reveals the results of a year-long study showing that Testosterone Replacement Therapy can significantly improve insulin sensitivity and sexual function in hypogonadal men suffering from Type 2 Diabetes and/or Metabolic Syndrome.

“The finding that Testosterone Replacement Therapy improves insulin sensitivity in a placebo-controlled study and that the effect persists over the 12 month treatment period is a very important clinical finding,” said lead author Professor Hugh Jones, Consultant Endocrinologist and Honorary Professor of Andrology at the University of Sheffield Medical School in the UK.

“Importantly, insulin resistance is associated not only with the development of high blood sugars but also hypertension and adverse abnormalities in the lipid profile as well as other biochemical changes which increase the risk of cardiovascular disease. Approximately three quarters of men with diabetes die as a result of cardiovascular disease. Any therapy which reduces insulin resistance, by inference should reduce the overall cardiovascular risk.”

Professor Jones presented the results of the study late yesterday in San Francisco at the ENDO 08 conference – the world’s largest gathering of endocrinologists.

This was a double-blind, placebo-controlled study among 220 hypogonadal men aged 40 and over and was carried out in eight European countries over a 12 month period. All the patients enrolled into the study had been previously diagnosed with Type 2 Diabetes and/or Metabolic Syndrome.

The study’s primary endpoint was to measure the effect of 2% testosterone gel on insulin sensitivity after six and 12 months. Its secondary endpoint was to assess changes in abdominal obesity; lipid profile; glycaemic control; sexual function; cardiovascular events; and safety and tolerability.

The principal results of the study were:

- A significant improvement in insulin sensitivity was observed among those using the testosterone gel, compared to placebo, after six months, and this was maintained at 12 months.
- Those using the testosterone gel saw a significant improvement in sexual function after six and 12 months.
- The testosterone gel treatment was well tolerated.

ProStrakan markets its novel, metered dose 2% testosterone gel, Tostran (also branded as Fortigel, Tostrex and Itnogen), in 13 countries across Europe as replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical symptoms and laboratory analyses. It plans to file for approval of the product in the US later in 2008.

Commenting on the study's results, Nigel Atherton, ProStrakan's VP of Global Development, said:

"The understanding of the medical benefits of Testosterone Replacement Therapy in hypogonadal males is growing rapidly. ProStrakan's TIMES2 study is one of the largest formal scientific investigations conducted in this field to date. The study demonstrated that the beneficial effects of Testosterone Replacement Therapy may extend beyond treatment of typical hypogonadal symptoms associated with testosterone deficiency to potentially impact other medically significant conditions such as Type 2 Diabetes and Metabolic Syndrome.

"Today's announcement of these major new findings adds substantially to the knowledge base in this area and highlights the importance of accurate diagnosis and treatment of male hypogonadism."

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For further information, please contact:

ProStrakan	+44 (0)1896 664103
Callum Spreng, Corporate Comms	
Financial Dynamics	+44 (0)20 7831 3113
David Yates / Ben Brewerton	
Trout Group (for US investor enquiries)	(646) 378-2949
Gitanjali Jain	

About ProStrakan

ProStrakan Group plc is a rapidly growing specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets.

ProStrakan's head office and development facilities are situated in Galashiels in Scotland. Sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, US, France, Germany, Spain and other EU countries. www.prostrakan.com

About the TIMES 2 Study

The TIMES 2 study was sponsored by ProStrakan to test, in a wider clinical setting, data from earlier, smaller studies that suggested Testosterone Replacement Therapy could improve insulin sensitivity (Kapoor D et al. European Journal of Endocrinology 2006; 154: 899-906.) in hypogonadal patients with Type 2 Diabetes and/or Metabolic Syndrome.

Metabolic Syndrome is commonly defined as a group of risk factors that include dyslipidaemia, obesity, hypertension and atherosclerosis, which are all linked to insulin resistance. Metabolic Syndrome is associated with a high risk of developing Type 2 Diabetes and cardiovascular disease.

The TIMES 2 study was a randomised, double blind, placebo controlled, multicentre and international study to assess the effect of daily transdermal testosterone replacement in hypogonadal men with Type 2 Diabetes and/or Metabolic Syndrome.

The primary endpoint of this study was to determine the effect of 2% testosterone gel (Tostran) on insulin resistance. This was measured by sampling the patients' blood after an overnight fast and measuring insulin and glucose levels to calculate HOMA-IR, an index of insulin resistance. Secondary endpoints included: change in lipid profile and abdominal obesity; glycaemic control as measured by HbA1c; cardiovascular risk score and sexual satisfaction and other quality of life scores.

The study ran in Belgium, France, Germany, Italy, Netherlands, Spain, Sweden and the UK. 220 patients were recruited, starting in 2005, and randomised to 2% testosterone gel treatment, or placebo gel, applied once a day to the thigh and abdomen. The study continued patients on treatment for one year.

About Hypogonadism

Hypogonadism in men occurs when the testosterone (male sex hormone) levels in the blood fall below normal. This can be part of the aging process or as a result of other medical conditions. Testosterone production by the testes can fail, or a decrease in testicular stimulation by the pituitary gland in the brain can also result in hypogonadism. The most common symptoms that patients experience include: fatigue, mood changes and depression, loss of libido and erectile dysfunction, reduced muscle strength and bone weakness. Hypogonadism can be treated by replacement of testosterone.

About Metabolic Syndrome

Metabolic Syndrome is an increasingly common condition throughout the world. It occurs when a range of metabolic risk factors come together in a single person. These risk factors generally include:

- **obesity** (generally in the abdominal region.)
- **insulin resistance or intolerance to glucose** (this means that the body cannot properly use blood sugar resulting in higher than normal blood glucose)
- **proinflammatory state** (inflammatory proteins in the blood, also contributing to insulin resistance)
- **atherogenic dyslipidaemia** (disorders in the blood fat, with high levels of 'bad' cholesterol and low levels of 'good' cholesterol)
- **high blood pressure**

People who suffer from Metabolic Syndrome are at a much greater risk of developing Type 2 Diabetes as well as other diseases. Metabolic Syndrome is extremely common in some areas of the world. Some estimates put the American figure for Metabolic Syndrome cases above 40 million.

About Type 2 Diabetes

Diabetes is a condition in which the glucose levels in the blood are abnormally high because the body cannot use it properly, due to a lack of the hormone insulin. Type 2 Diabetes develops when the body can still produce insulin, but the insulin that is produced does not have a normal effect (insulin resistance). In most cases this is linked with being overweight. This type of diabetes is usually diagnosed in people over the age of 40. Type 2 Diabetes is the most common type of diabetes and accounts for between 85% - 95% of all people with diabetes.

About Tostran

Tostran is the first metered dose 2% testosterone gel for use as replacement therapy in male hypogonadism, a condition with serious consequences and associations. Following its launch in Sweden in 2005, where it has over 30% of the testosterone gel market, Tostran is now available in all main European countries.