Novo Nordisk obesity drug trial confirms weight loss

28 May 2013 | News | By BioSpectrum Bureau

Singapore: Novo Nordisk's 56-week double-blind phase IIIa clinical trial with liraglutide has shown that it has the potential to induce and maintain weight loss in people without diabetes, who are obese or overweight with comorbidities such as prediabetes, hypertension and dyslipidaemia. This is the third phase IIIa trial to be completed as part of Scale, which is the clinical development programme for liraglutide 3 mg for obesity treatment.

In the trial, 3,731 overweight or obese people were randomized 2:1 to treatment with liraglutide 3 mg or placebo, both in combination with diet and exercise. In the trial, people without signs of prediabetes were treated for 56 weeks, followed by a 12-week follow-up period. People with signs of prediabetes at the time of randomization are currently continuing treatment for two additional years. The announced results are for all people at 56 weeks.

Finally, people treated with liraglutide 3 mg experienced statistically significant improvements in obesity-related risk factors, including blood pressure, cardiovascular risk biomarkers, lipids and patient-reported quality of life, compared to people treated with placebo. Withdrawals due to adverse events were below 10 percent in both treatment groups. The most common adverse events were related to the gastrointestinal system and they diminished over time.

Dr Mads Krogsgaard Thomsen, executive VP and chief science officer, Novo Nordisk, "We are very pleased with the results of this trial," said. "These data, together with previously reported phase 3 trials, consistently demonstrate clinically significant weight loss and improvements in obesity-related risk factors in people with obesity."

Novo Nordisk expects to complete the remaining phase IIIa trial in the Scale programme during the third quarter of 2013 and to file liraglutide 3 mg for regulatory review as a treatment for obesity in the US and EU around the turn of the year.