metabolic

Press Release

Successful trial results for world-first obesity drug

Monday 13 December 2004, Melbourne Australia: An Australian-owned obesity drug, developed by Melbourne-based biotechnology company Metabolic Pharmaceuticals Limited, is set to enter final human trials next year after successfully completing a Phase 2b human trial which proved that the drug induces weight loss and is very well tolerated with no evidence of the side effects commonly experienced with existing obesity drugs.

The drug, which stimulates the metabolism of body fat, is the first of its kind in the world. All other obesity drugs artificially reduce appetite or food absorption.

The drug – codenamed AOD9604 – was taken orally once daily by 300 obese patients at five trial sites over a 12-week period. Six doses were used – 0 mg (placebo), 1mg, 5 mg, 10 mg, 20 mg and 30 mg.

The group receiving the 1mg dose lost the most weight, averaging a weight loss over the 12 weeks of 2.8 kilograms, more than triple the weight lost by those on placebo, who lost an average of 0.8 kilograms. The rate of weight loss was maintained throughout the treatment period, an encouraging trend for expectations of longer-term dosing.

The weight lost by the 1mg group was slightly more than that achieved by the world's largest selling prescription obesity medication in similar trials over the same period, without its troublesome side effects. The trial results also demonstrated a small but consistent improvement in cholesterol profiles, and a reduction in the number of patients with impaired glucose tolerance.

Obesity is the Western World's most common health problem, and has reached epidemic proportions according to the World Health Organisation. More than 20% of the adult population in developed countries are obese – more than 300 million adults worldwide. In addition, more than 50% of adults in developed countries are overweight. Obesity is associated with other health-related problems such as heart disease, cancer and diabetes.

AOD9604 is based on a small part of the human growth hormone molecule. This hormone, which occurs naturally in the body and which stimulates fat metabolism, is suppressed in obese people.

"We are delighted with these results," stated Metabolic Pharmaceuticals CEO, Chris Belyea. "The evidence from the trial is that over 12 weeks AOD9604 induces competitive weight loss with accompanying health benefits at a low dose and has superior tolerability. Our next major focus is a partnership with a major pharmaceutical company to assist in financing late stage longer term human clinical trials for worldwide marketing approval as a prescription treatment."

Prof. Gary Wittert, Adelaide-based Principal Investigator on the study, said: "As the world's first drug with a metabolic mechanism of action AOD9604 could occupy a unique position among the options available to doctors for the management of obesity. It is pleasing that the invention and its development from the laboratory bench has been an all–Australian effort."

Prof. Louis J Aronne MD, President of the North American Association for the Study of Obesity and a member of Metabolic's Clinical Advisory Panel, said: "This is an exciting new approach to a problem which has defied easy solutions. We will need many different treatments if we are going to manage obesity successfully, in much the same way we have many treatments available for diabetes and hypertension".

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