



Medical Products Agency permit a Phase II clinical trial with the Diabetes vaccine Diamyd™ in children who have recently succumbed to insulin-dependent diabetes

Diamyd Medical (O-listan) will immediately begin studies in a new treatment area for their diabetes therapeutic/vaccine Diamyd™. The Swedish MPA in Uppsala and the regional ethical committee in Linköping have agreed to a Phase II clinical study involving 70 children and adolescents who have recently succumbed to insulin-dependent, type 1 diabetes. The purpose of the study is to investigate if the remaining pancreatic insulin-producing beta cells can be saved through two immunizations of Diamyd™. This could lead to remission of disease, i.e. that the requirement for external insulin injection is minimized or removed entirely.

The multicentre study will commence immediately at diabetes clinics in Linköping, Jönköping, Borås, Malmö, Halmstad, Örebro, Queen Silvias children's hospital in Göteborg and at the Astrid Lindgren hospital in Stockholm. The study is headed by Professor Johnny Ludvigson of Linköping University. The patients included in the study are children and adolescents between 10-18 years of age who have not been diagnosed with diabetes for longer than 18 months. The study is double-blind, random and placebo-controlled.

"This is great news! I could never have dreamed that a molecule that we, in collaboration with Professor Åke Lernmark's research group more than 20 years ago, were the first in the world to detect in diabetic children and which later was shown to be GAD, could give us hope to radically improve the treatment of diabetic children! If GAD vaccination has the effect we hope for then this will be a significant advance towards a better treatment of and life quality for diabetic children! If residual insulin producing capacity is preserved then the disease course should be lessened, as will the risk for complications. This will also indicate the long-term prospect of preventing juvenile diabetes", says Professor Ludvigsson.

Through this new study Diamyd Medical expands its development of clinical therapeutics to include both type 1 and type 2 diabetes. The potential of these applications is significant. Data from the company's recent Phase II clinical trial with Diamyd™ implicates that vaccination allows protection of the insulin-producing beta cells from destruction by the immune system. This then permits recovery of beta cells and their survival, which should in turn reduce the need for use of external insulin supplementation.

"This Type 1 diabetes study in children and adolescents can represent a breakthrough for antigen-specific treatment of autoimmune diseases. If we succeed then through a vaccination-like treatment we will completely change

the treatment of insulin-dependent diabetes. Instead of daily injections for the rest of their life we will instead be able to inject patients a couple of times, which will signify a significant improvement in quality of life for the children", says Diamyd Medicals' medical chief Dr. Ann-Sophie Bennet.

Diamyd Medical is even currently conducting a pivotal Phase II/III clinical trial of type 2 diabetes patients with GAD-specific antibodies (so-called LADA patients). Over 2 000 patients have applied to be part of this study and screening is ongoing in order to select a total of 160 patients for inclusion in the study, a few of these already having received the first treatment. In an earlier Phase II clinical study of 47 LADA patients an effective dose was identified which is now used in both of the new studies. Professor Carl-David Agardh (Malmö Hospital) reported at the American diabetes congress ADA in June 2004 that two injections of 20ug Diamyd™ gave positive results, currently up to two years after treatment, with respect to both insulin production and blood glucose levels.

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