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Diamyd's retogatein delays insulin requiring Type-1 Diabetes for more than 5 years

Long-term follow-up of the randomized, placebo-controlled DiAPREV-IT study, now in press in Diabetologia, shows that two subcutaneous injections of retogatein (GAD-alum) significantly delayed Stage 3 Type 1 Diabetes by over five years in a genetically defined subgroup of children.

"These results support retogatein as a potential disease modifying therapy for children with GAD-antibodies and at least one more islet autoantibody and belonging to a genetically defined responder group" says Helena Elding Larsson, Professor at Lund University, Sweden.

The study was led by Professor Helena Elding Larsson (Lund University and Skåne University Hospital, Malmö). Long-term follow-up (median of 12.9 years) was conducted on patients in the DiAPREV-IT trial. Here two subcutaneous injections of retogatein-alum (GAD-alum) were compared with placebo for delaying the progression to Stage 3 (insulin requiring) Type 1 Diabetes in 50 children at risk for developing the disease (classified as Stage 1 or Stage 2). In participants belonging to a genetically defined subgroup (HLA DR3-DQ2), retogatein significantly delayed time to Stage 3 Type 1 Diabetes ($p=0.018$), with an estimated median time of 9.0 years compared to 3.4 years with placebo. A delay of more than 5 years.

The DiAPREV-IT study was initiated in individuals with Stage 1 or Stage 2 Type 1 Diabetes, that is when the individuals were still not depending on receiving daily external insulin. Here the retogatein was given as two injections under the skin (subcutaneously). This differs from the Phase 3 DIAGNODE-3 trial, which evaluated intralymphatic administration in already insulin-requiring patients with recent-onset Stage 3 Type 1 Diabetes. These differences in timing and route of administration, where lymph node injections may require special training, are relevant when considering when and how retogatein immune precision medicine is best administered.

"These long-term results, together with retogatein's demonstrated good safety profile in more than 1,000 patients, the ease of treatment, the specific autoantigen tolerance induction (instead of immunosuppression), provide a strong rationale for confirming retogatein's effect in children with GAD antibodies and the relevant genetic profile. They signal the potential for retogatein, in helping children in need, giving them extra years without the need of external insulin, - as well as potentially a longer life expectancy" says Anders Essen-Möller, CEO at Diamyd Medical.

Publication details: The results of the above-described long-term follow-up study will be published in *Diabetologia*, titled "*Delayed time to stage 3 type 1 diabetes after GAD-alum treatment in HLA-DR3-DQ2-positive children: follow-up of the randomized placebo-controlled Diabetes Prevention - Immune Tolerance trial*".

About DiAPREV-IT

DiAPREV-IT (EudraCT 2008-007484-16) evaluated primarily the safety of two subcutaneous injections of retogatein-alum (vs placebo) as well as efficacy in preventing the progression to Stage 3 Type 1 Diabetes in 50 children aged 4-18 years, positive for GAD autoantibodies and at least one more islet autoantibody and classified as Stage 1 or Stage 2 Type 1 Diabetes, over a 5-year trial period. Results of the trial were published in 2017 in *Pediatric Diabetes* (<https://onlinelibrary.wiley.com/doi/10.1111/pedi.12611>).

About Diamyd Medical

Diamyd Medical is a Swedish biotechnology company focused on precision medicine approaches for type 1 diabetes and biological manufacturing. The company's lead investigational drug candidate is retogatein (GAD-alum), based on recombinant GAD65. The Company has established a GMP-approved facility for manufacturing of biological products in Umeå, Sweden. Diamyd Medical's B share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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