



Press release, November 26, 2018

## **Eleven out of twelve Type 1 diabetes patients treated with intralymphatic Diamyd® are in Partial Remission at 15 months**

*Diamyd Medical announces that a further analysis ahead of the upcoming conference 1<sup>st</sup> Antigen Specific Immune Tolerance Europe in London 11-12 December shows that 92% (11 out of 12) of the DIAGNODE-1 trial participants are in Partial Remission at 15 months from start of the trial. This can be compared to a large international study in 3657 children and adolescents with type 1 diabetes, where approximately 20% of the patients were in partial remission 12 to 18 months after diagnosis. Partial remission in type 1 diabetes is characterized by low external insulin requirement and near to normal long-term blood sugar levels.*

Research shows that in type 1 diabetes any ability to secrete insulin is of paramount importance for the patient, as even a small endogenous production has been shown to reduce long-term complications as well as to reduce acute afflictions such as hypoglycemia.

After diagnosis and commencement of exogenous insulin therapy, most patients enter into a so called honeymoon period or partial remission, characterized by low need for exogenous insulin due to improved insulin sensitivity and/or endogenous secretion, while long-term blood sugar (HbA1c) is maintained at near to normal levels. Development of immunomodulatory therapies, that downregulate the inflammation in pancreatic islet cells and support the function and regeneration of insulin producing beta cells are considered of greatest importance for the prolongation of this partial remission period.

Nagl et al, 2017, Pediatric Diabetes (<https://onlinelibrary.wiley.com/doi/abs/10.1111/pedi.12413>), found in a large cohort of 3657 type 1 diabetes patients, that Partial Remission as defined by insulin adjusted HbA1c (IDAA1c) occurred in 22% at time of diagnosis; 61% at 3 months, 46% at 6 months, 28% at 12 months, 18% at 18 months, 13% at 2 years, 9% at 3 years, 6% at 4 years, and 5% at 6 years. Nagl et al further reported that patients aged 5 years and above had twice the chance to enter into Partial Remission. Though patients below the age of 5 showed a lower chance of entering Partial Remission, no difference was seen in the number of patients in Partial Remission after 12 months based on age at diagnosis.

As previously announced from the DIAGNODE-1 trial, when Diamyd® is administered directly into the lymph node, a clinically relevant positive effect has been seen in improving the clinical course and maintaining the endogenous insulin production in newly diagnosed type 1 diabetes. The current analysis shows that 11 out of the 12 patients in DIAGNODE-1 are in partial remission after 15 months from inclusion in the trial. This equals an average of approximately 18 months from time of diagnosis. Results from DIAGNODE-1 and previous trials will be presented at the 1<sup>st</sup> Antigen-Specific Immune Tolerance Europe in London on December 11 – 12, 2018.

### **About Diamyd Medical**

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in trials with more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase-II trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, there are four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen®, an oral GABA-based investigational drug. An investigator-initiated trial in patients with type 1 diabetes since at least five years has started at Uppsala University Hospital. An investigator-initiated placebo-controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham. Exclusive licenses for GABA and positive allosteric modulators of GABA receptors for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen® key assets. Diamyd Medical is also one of the major shareholders in the stem cell company NextCell Pharma AB and has

holdings in the medtech company Companion Medical, Inc., San Diego, USA and in the gene therapy company Periphagen, Inc., Pittsburgh, USA.

Diamyd Medical's B-share is traded on Nasdaq First North under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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