



Press release, January 8, 2018

The diabetes vaccine Diamyd® shows continued positive clinical course after 30 months

Positive effects such as lower insulin requirements and improved blood glucose levels are observed for the first four diabetes patients that have been followed for 30 months in the DIAGNODE-1 trial. Safety looks good and no serious side effects have been reported.

In a fifth interim report from the open label investigator initiated clinical pilot trial DIAGNODE-1, where the diabetes vaccine Diamyd® is administered directly into the lymph node, results are presented for the first four patients that have been followed for the entire study period, 30 months. No serious side effects have been reported and positive effects are seen on the disease progression. On average, the patients' own ability to produce insulin (measured by C-peptide, AUC) has decreased by 32%, while at the same time, patients have on average lower (-15%) long-term blood sugar (HbA1c) and use less insulin (-22%) than at the start of the trial. In summary, these data indicate that the disease progression continues to be positive at 30 months for these first four patients.

"The results show that the endogenous insulin production after 30 months is higher than expected," says Johnny Ludvigsson, Professor at Linköping University and Principal Investigator of the trial. "We know that remaining insulin production is important and here we see the first results from intralymphatic treatment that indicate a positive effect that persists for more than two years after the last treatment".

About DIAGNODE-1

DIAGNODE-1 is an open label pilot trial, comprising a total of twelve patients between the ages of 12 and 30 with type 1 diabetes, where the diabetes vaccine Diamyd® is administered three times, one month apart, in a low (4µg) dose directly into the lymph node. The treatment is combined with oral vitamin D. Twelve patients have been followed for 6 months and out of these six patients have been followed for 15 months from inclusion and four have been followed for the entire study period, 30 months.

About DIAGNODE-2

DIAGNODE-2 is a follow-up on DIAGNODE-1, where preliminary results show a positive clinical progression and desired immunological response as the diabetes vaccine Diamyd® is given directly into the lymph node. DIAGNODE-2 is a double-blind randomized trial encompassing approximately 80 patients from Sweden, the Czech Republic and Spain, aged 12–24 years that have recently been diagnosed with type 1 diabetes. The patients will be followed for 15 months with the aim to evaluate the remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University. Diamyd Medical is the Sponsor of the trial.

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 studies of 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™, a proprietary GMP manufactured oral GABA-based study drug. 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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