



Press release, September 7, 2016

## **Diamyd Medical provides update on clinical studies with Diamyd®**

*Diamyd Medical (Nasdaq First North, Stockholm, DMYD B) participates in six clinical studies with the diabetes vaccine Diamyd® for the treatment and prevention of type 1 diabetes. The Company announced today that yet another of these, the phase II study EDCR IIa now is fully enrolled and that results from a first evaluation after 6 months are estimated to be presented during the second quarter of 2017. The Company also announced that results from the placebo-controlled prevention study DiAPREV-IT 1 are expected to be presented during the first quarter of 2017.*

All 20 patients are now included in the Phase II study EDCR IIa (Etanercept-Diamyd®-Combination-Regimen), which runs at eight pediatric diabetes clinics in Sweden. The study is an open label clinical pilot study in children and adolescents aged 8 to 18 years with newly diagnosed type 1 diabetes where the diabetes vaccine Diamyd® is combined with two other already approved substances, etanercept and vitamin D. The study will last 30 months after all patients have been included. The purpose of the study is to evaluate the safety of the combination treatment and its effects on the immune system in children and adolescents with recent-onset type 1 diabetes. A first evaluation will be conducted after 6 months with a focus on immunological markers, the 6-month analysis will be able to start at the end of the first quarter of 2017 and the results thus be presented in the second quarter of 2017. The study is led by Professor Johnny Ludvigsson at Linköping University, principal investigator and sponsor of the study.

The study is part of a series of combination studies with the diabetes vaccine Diamyd® to enhance the efficacy (16%,  $p=0.1$ ) previously achieved in a European Phase III study of 334 newly diagnosed type 1 diabetes patients. The Phase II study EDCR IIa is the first of its kind where the diabetes vaccine Diamyd® is combined with etanercept and vitamin D, and tested against the complex autoimmune process that causes type 1 diabetes.

Etanercept is a so-called TNF-alpha inhibitor used in rheumatic diseases and is approved among other things, to treat children with juvenile idiopathic arthritis (JIA). Data from previous clinical studies indicate that Diamyd® activates components that down-regulate inflammation and certain components that can activate the immune system. By combining the diabetes vaccine with etanercept, the inflammatory response is reduced and the diabetes vaccine tolerance inducing effect thus have a greater impact. Vitamin D is intended to further down-regulate the immune system's inflammatory components in order to strengthen the regulatory effect of the diabetes vaccine. Both vitamin D and etanercept are also considered to have a direct positive effect on the beta cells.

In the placebo-controlled study DiAPREV IT-1, the last patient is expected to make its last visit in late 2016, where after the study results will be processed and analyzed before the results can be presented in the first quarter of 2017.

Ongoing, also fully enrolled, is the placebo-controlled study DIABGAD in which results are expected in the first quarter of 2017. Not yet fully enrolled studies are the placebo-controlled GABA/Diamyd® study, the open label study DIAGNODE-1 and the placebo-controlled study DiAPREV-IT 2.

### **About Diamyd® and combination trials**

Type 1 diabetes is a devastating disease which requires daily treatment with insulin to sustain life. The importance of finding a cure should not be underestimated. The diabetes vaccine Diamyd® has been used in clinical studies with more than 1,000 patients and has shown a good safety profile. In a European Phase III trial Diamyd® showed good clinical effect in several subgroups, and a limited overall 16% efficacy ( $p=0.10$ ) in preserving endogenous insulin secretion. Subsequent development is focused on combination trials to enhance efficacy. Diamyd® is easy to administer in any clinical setting. The potential annual market is estimated to several billion dollars per year.

Six researcher initiated clinical trials are ongoing combining Diamyd® with various other immunomodulatory compounds; etanercept, ibuprofen, vitamin D and GABA.

- **DIABGAD-1 – COMBINING DIAMYD® WITH IBUPROFEN AND VITAMIN D**  
A placebo-controlled trial, where Diamyd® is being tested in combination with ibuprofen and vitamin D. The trial comprises a total of 64 patients between the ages of 10 and 18, recently diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the combination treatment is to preserve the body's own capacity to produce insulin. The trial runs at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University, Sweden. 30 month results from the trial are expected during the first quarter of 2017.
- **DIAGNODE-1 –DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D**  
An open label trial, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial comprises nine patients between the ages of 12 and 30 newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University, Sweden. The first patient was included in the trial in February 2015.
- **GABA/DIAMYD® – COMBINING DIAMYD® WITH GABA**  
A placebo-controlled trial, where Diamyd® is being tested in combination with GABA. The trial comprises 75 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes, and will continue for a total of 12 months. The aim of the combination treatment is to preserve the body's residual capacity to produce insulin. The trial is led by Dr. Alexandra Martin at the University of Alabama at Birmingham, USA. The first patient was included in the trial in March 2015.
- **EDCR IIa – COMBINING DIAMYD® WITH ETANERCEPT AND VITAMIN D**  
An open label trial, where Diamyd® is combined with etanercept and vitamin D. The trial comprises 20 patients between the ages of 8 and 18 who have been newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University, Sweden. All patients were included in September 2016 and 6 month results are expected during the second quarter of 2017.
- **DiAPREV-IT 1– DIAMYD®**  
A placebo-controlled trial, where Diamyd® is being tested in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing autoimmune process but do not yet have any clinical symptoms of diabetes. A total of 50 participants from the age of four have been enrolled in the trial, which will last for five years. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden. Five year results are expected during the first quarter of 2017.
- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**  
A placebo-controlled trial, where Diamyd® is being tested in combination with vitamin D in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing autoimmune process but do not yet have any clinical symptoms of diabetes. A total of 80 participants between the ages of 4 and 18 will be enrolled in the trial, which will last for five years. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden. The first patient was included in March 2015.

#### **About Diamyd Medical**

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

Diamyd Medical develops the diabetes vaccine Diamyd®, an Antigen Based Therapy (ABT) based on the exclusively licensed GAD-molecule. The Company's licensed technologies for GABA and Gliadin have also

potential to become key pieces of the puzzle of a future solution to prevent, treat or cure autoimmune diabetes, and also certain inflammatory diseases. At this time six clinical studies are ongoing with Diamyd®. Diamyd Medical is one of the major shareholders in the stem cell company Cellaviva AB. Stem cells can be expected to be used in Personalized Regenerative Medicine (PRM), for example for restoration of beta cell mass in diabetes patients where the autoimmune component of the disease has been arrested. Diamyd Medical also 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 Stockholm First North under the ticker DMYD B. Remium Nordic AB is the Company's Certified Adviser.

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