Press release, December 17, 2015

Preliminary 15-month results from DIABGAD – a 30-month pilot study with the diabetes vaccine Diamyd® in combination with vitamin D and ibuprofen

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) today announced from a clinical investigator-initiated pilot study, DIABGAD-1, that the diabetes vaccine Diamyd® in combination with vitamin D and ibuprofen after 15 months has a good safety profile with no reported serious side effects related to the treatment. The data shows that after the initial phase (referred to partial remission or the honeymoon phase), the group receiving placebo (non-active substance) lost their ability to produce insulin at a rate that was 2-3 times faster during the last 9 months of the 15-month period, compared with the groups receiving active treatment with Diamyd®. However, viewed over the entire 15-month period no difference between the groups is observed, but if the more rapid decrease continues in the placebo group until the end of the study at 30 months, a trend deviation in insulin production may be observable throughout the full measurement period, that is, including the remission period.

The DIABGAD-1 study, which is the first of its kind, combines the diabetes vaccine Diamyd® with vitamin D and the anti-inflammatory drug ibuprofen, and is conducted at nine pediatric diabetes clinics in Sweden, with Professor Johnny Ludvigsson, Linköping University, as the principal investigator and sponsor.

The purpose of the pilot study is to test the combination therapies' safety and how they impact the body's own ability to produce insulin in children and adolescents newly diagnosed with type 1 diabetes. The participants will be monitored for 30 months.

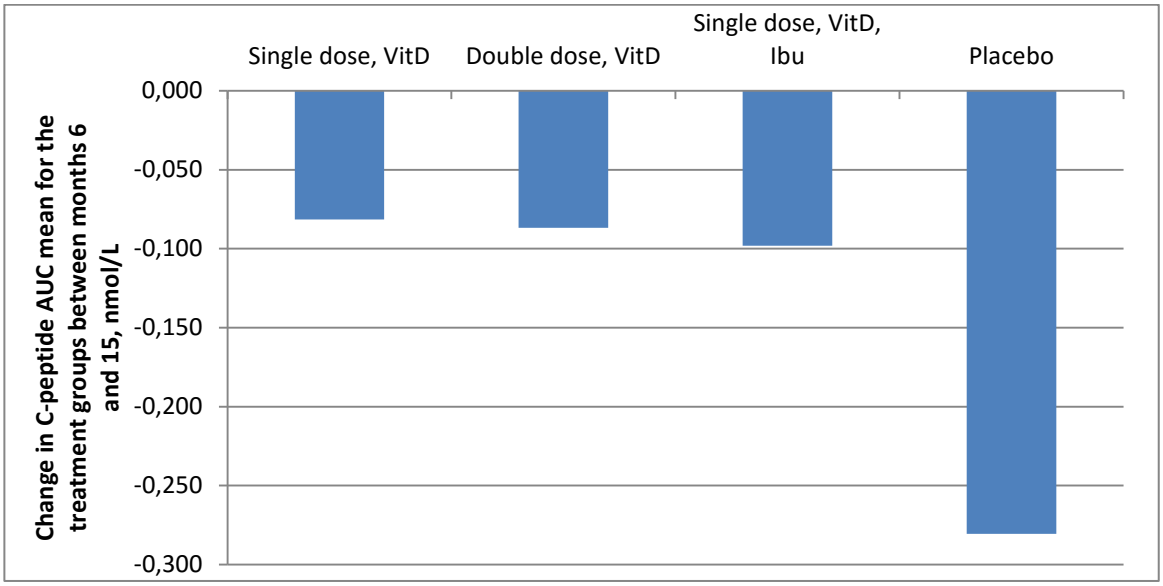
"It is clearly interesting that the fall-off in the ability to produce insulin is slower among patients receiving active treatment during the 6-15 month period of the study, that is, following the usually relatively stable initial half year after diagnosis," says Professor Johnny Ludvigsson at Linköping University, who is the principal investigator and sponsor of the study. "If this trend persists, our combination therapy may show results in another 15 months that are clinically significant."

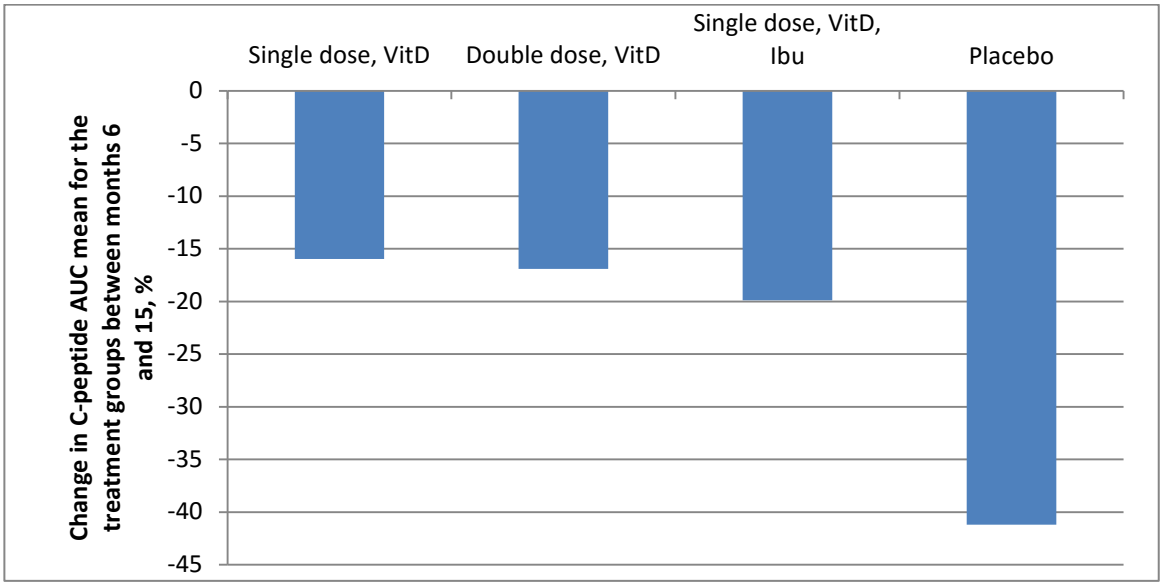
The preliminary 15-month results indicate that the safety of the combination therapy is good and no serious adverse events related to the treatment have been reported.

Following the start of insulin treatment, many type 1 diabetes patients enter partial remission which, depending on age, can extend over a period of a few months up to a couple of years (*Pecheur et al., J Diabetes Research, 2014:851378*). For this reason, the effects of the various combination therapies is presented below as the difference in the insulin-producing capacity between the date for the 6-month visit after inclusion in the study, which is close to the mean value for the length of the stable phase (partial remission), and the visit 15 months after inclusion in the study. Over the course of these 9 months, the ability to produce insulin (measured as C-peptide Area Under the Curve (AUC) in nmol/L) decreases in the placebo group at a rate that is 2-3 times faster than the groups treated with Diamyd®. If this more rapid decrease continues among the placebo group until the end of the study at 30 months, a trend deviation in insulin production may be observable throughout the complete measurement period, that is, including the remission period.

"You have to keep in mind that this is a small study and we have only obtained descriptive data from the 15-month results, meaning no formal analysis has been performed. Furthermore, the remission period could be playing tricks on us. All of this means that it is far too early to celebrate," says Anders Essen-Möller, President and CEO of Diamyd Medical. "But we are certainly cautiously excited about the results that Johnny's team has observed from month 6 and onward, and we are carefully monitoring developments from month 15 to 30 given that this is an important part of the puzzle in the work pursued by Diamyd through its many studies."

From the date of inclusion up to 15 months, meaning including the estimated remission period, no difference in insulin production, measured as C-peptide AUC, is observable between the groups. However, measured from month 6 to month 15, the capacity to produce insulin declined in the placebo group (n=10) by 0.28 nmol/L (41%), while the group that received Diamyd®, vitamin D and ibuprofen (n=11) declined by 0.10 nmol/L (20%); the group receiving Diamyd® and vitamin D (n=15) declined by 0.08 nmol/L (16%), and the group that received a double dose of Diamyd® and vitamin D (n=14) declined by 0.09 nmol/L (17%).





In a previous Phase III study (n=334), treatment with the diabetes vaccine Diamyd® alone was shown to yield a positive trend (16% effect, p=0.1) in terms of the patients' own ability to produce insulin. To achieve a better effect, the diabetes vaccine is therefore being tested as part of various combination therapies in several different pilot studies. The efficacy and safety of initially positive combinations should thereafter be validated in larger studies in order to be approved as a treatment.

The DIABGAD study comprises approximately 60 patients between the ages of 10 and 18 newly diagnosed with type 1 diabetes, randomized to four treatment groups, for which C-peptide data is available for 50 patients at 15 months. The first group received one injection of Diamyd® 20µg on two occasions four weeks apart combined with ibuprofen over the course of 90 days, in addition to vitamin D for a period of 15 months; the second group received one injection of Diamyd® 20µg on two occasions four weeks apart combined with vitamin D for a period of 15 months; the third group received a double dose of Diamyd® four weeks apart and vitamin D for 15 months and; the fourth group received placebo only. Enrollment in the study, which is double-blind, randomized

and placebo-controlled, commenced in February 2013. All participants have now been monitored for 15 months of the 30-month total for the study.

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. Diamyd Medical is one of the major shareholders in the stem cell company Cellaviva AB, active in private family saving of stem cells from the umbilical cord. 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 by ABT.

Six researcher-initiated clinical studies with Diamyd® in different treatment regimens are ongoing:

- **DIABGAD- 1 – COMBINING DIAMYD® WITH VITAMIN D AND IBUPROFEN**

INTERVENTION TRIAL
A placebo-controlled trial, where Diamyd® is being tested in combination with vitamin D and ibuprofen. The trial comprises approximately 60 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 due during the first half year of 2017.

- **DIAGNODE -1 –DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D**

INTERVENTION TRIAL
An open label trial, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial comprises five patients between the ages of 18 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**

INTERVENTION TRIAL
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 Professor Kenneth McCormick 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**

INTERVENTION TRIAL
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, 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 May 2015.

- **DiAPREV-IT 1– DIAMYD®**

PREVENTION TRIAL

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 at the end of 2016.

- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**

PREVENTION TRIAL
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.

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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