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New study to prevent type 1 diabetes planned for Diamyd Medical's diabetes vaccine

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that a new study is planned for the Diamyd® diabetes vaccine that will comprise 80 children with high risk of presenting with type 1 diabetes. The aim is to test whether the diabetes vaccine can prevent or delay the onset in the children. To increase the possibilities of demonstrating efficacy for Diamyd®, a decision has also been taken to keep the ongoing prevention study DiAPREV-IT intact and blinded until all 50 children involved have been monitored for five years, toward the end of 2016. Thus far, 14 children have been diagnosed with type 1 diabetes in this study, which is fewer than expected.

“The planned strategy means that more children who have entered the autoimmune process, but who have not yet been diagnosed with type 1 diabetes, can obtain access to the diabetes vaccine both prior to and following any diagnosis,” says Anders Essen-Möller, Chairman of Diamyd Medical. “This could shorten the path to market acceptance.”

In order to increase the scientific value of the research on preventative treatment with the Diamyd® diabetes vaccine, the research team at Lund University, who have been driving the DiAPREV-IT study since 2009, decided to expand the dataset with additional children at high risk of presenting with type 1 diabetes. Therefore, after discussions with the Swedish Medical Products Agency and Diamyd Medical, a new, larger study of a similar design to DiAPREV-IT is being planned, in which new research findings are taken into consideration.

“We have discovered that children with a high risk of presenting with type 1 diabetes can be divided into two distinct groups already at screening: those with a normal and those with an impaired glucose metabolism. Furthermore, almost all 14 children that have been diagnosed with type 1 diabetes in the ongoing DiAPREV-IT study belong to the latter group,” says Dr. Helena Elding Larsson, pediatrician in Malmö and researcher at Lund University but also the lead investigator and sponsor for both studies. “This discovery, combined with the fact that 14 out of 50 children was fewer than we had expected to have presented with type 1 diabetes by this stage, means that the scientific value of the ongoing study increases substantially through us keeping the study blind for a further two years. This implies that the statistical base of children who have presented with the disease in the study will increase. By planning a new study with, in principle, the same design, but where the two groups we recently identified are taken into account, we further increase the chance of being able to ascertain any efficacy for the Diamyd® diabetes vaccine.”

The new study, named DiAPREV-IT 2, is a researcher-initiated study comprising 80 children aged four and above with a 50-percent risk of developing clinical symptoms of type 1 diabetes within five years. The study is double-blind and placebo-controlled, which means that half of the children will receive two doses of Diamyd® and half will receive placebo (non-active substance). No-one will know who has received what until the end of the five year study. The intent is to see if the diabetes vaccine can prevent or delay the onset of clinical symptoms of type 1 diabetes in the children. Simply delaying the onset of the disease with the help of Diamyd® would be a major medical success. Those children that develop clinical symptoms of type 1 diabetes during the study

will receive injections of active Diamyd® after diagnosis, irrespective of whether they have received active or placebo as preventative treatment. In this manner, it will also be possible to follow the efficacy of the diabetes vaccine in new-onset patients.

The study will be much like the ongoing DiAPREV-IT study, except that supplementation of vitamin D is included for all participants and that the latest findings, namely that two early stages of type 1 diabetes exist prior to clinical onset, have been taken into account. The study will stratify the participants according to the stage they belong to at the start of the study. The first stage comprises children with two or more auto-antibodies directed at their own insulin-producing cells, but with normal glucose metabolism. The other stage is children with both auto-antibodies and an impaired glucose metabolism. Vitamin D supplement is given to lower the immune system's inflammatory components to, thereby, increase the diabetes vaccine's tolerance-inducing effect with the aim of maintaining the ability to produce insulin.

“In large screening studies, we have identified many children that, sooner or later, will present with type 1 diabetes,” says Åke Lernmark, Professor of Experimental Diabetes Research at Lund University. “It is frustrating to be unable to do anything to arrest this and, therefore, it is satisfying to offer these children the opportunity to be part of a study that includes a treatment, which we hope will help. Treatment with Diamyd® is extremely simple and has demonstrated a favorable safety profile in small children. In addition, I believe strongly in the addition of vitamin D.”

About DiAPREV-IT

Diabetes Prevention – Immune Tolerance (DiAPREV-IT) is a double-blind, randomized and placebo-controlled Phase II study comprising 50 children aged four and above, who, through the analysis of diabetes markers, so-called auto-antibodies, in the blood are demonstrated to be at high risk of presenting with type 1 diabetes. Half of the children have received two injections of the Diamyd® diabetes vaccine and the remaining half have received placebo (non-active substance). The children will be monitored for a period of five years. Results from the study are expected at the end of 2016. Thus far, 14 of the children have been diagnosed with type 1 diabetes.

The study is being conducted by a research team at Lund University and is funded by research grants. Diamyd Medical is providing the study drug and has participated in the design of the study and is also able to utilize the findings of the study.

About type 1 diabetes

Type 1 diabetes is an autoimmune disease where the immune system attacks the patients' own insulin producing beta cells. By analyzing markers in the blood it is possible to identify persons in whom the autoimmune process is ongoing, but has not yet caused clinical symptoms of type 1 diabetes. When clinical symptoms have developed, these patients must be treated daily, for the rest of their lives, with insulin to sustain life. The importance of finding a cure is high for the world's health care systems and the wellbeing of patients. The annual market for an easy to use, successful therapeutic is estimated to several billion dollars.

About Diamyd Medical

Diamyd Medical is dedicated to fight type 1 diabetes and to work towards a cure for the disease. Diamyd Medical's current projects include development of combination regimens for arresting the successive destruction of insulin producing beta cells using the Company's GAD65-based diabetes vaccine Diamyd®, such as Diamyd® + Vitamin D with or without an anti-inflammatory compound; and Diamyd® combined with GABA, for which Diamyd Medical licenses exclusive intellectual rights from the University of California in Los Angeles (UCLA). Diamyd Medical has further acquired 46% of the stem cell company Cellaviva AB that is establishing a Swedish commercial

bank for private family saving of umbilical cord blood and other sources of stem cells. Stem cells are required for Personalized Regenerative Medicine (PRM), for example to restore beta cell mass in diabetes patients where autoimmunity has been arrested.

Remium Nordic AB is the Company's Certified Adviser.

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