

Press Release, February 16, 2009

## Diamyd receives new approval for study to follow Swedish children and confirm long-term effect of the Diamyd<sup>®</sup> diabetes vaccine

Diamyd Medical has received approval from the Swedish Medical Products Agency to continue to follow the children who participated in the company's Phase II study of the Diamyd<sup>®</sup> diabetes vaccine, which started four years ago. The aim of the follow-up study is to confirm the vaccine's long-term effect.

"Clinical studies with Diamyd<sup>®</sup> have demonstrated significant efficacy in preserving the body's own ability to produce insulin," says Elisabeth Lindner, President and CEO of Diamyd Medical. "We will now, in parallel with our ongoing large international Phase III trials, establish that the treatment also has the intended long-term effect in the patient's daily life."

It's been nearly four years since the children and adolescents were treated with the Diamyd® vaccine, and now a three year follow-up will be offered. The children and adolescents will thus be followed for a total of seven years. The aim of the follow-up is to confirm that treatment with Diamyd® provides long-term clinical effect. The follow-up will evaluate control of blood sugar, insulin requirement, quality of life and diabetes complications.

The main results of the Phase II study were published in the scientific journal *The New England Journal of Medicine* in October 2008.

Today the worldwide cost of treating diabetes and its complications exceeds USD 230 billion per year. Approximately 20 percent of all diabetes is autoimmune diabetes, where the body's own immune system destroys insulin-producing cells. Clinical studies have demonstrated that treatment with Diamyd<sup>®</sup> halts or slows the destruction of the ability to produce insulin. *The Diabetes Control and Complications Trial*, a large American type 1 diabetes study, has demonstrated that a small amount of preserved endogenous insulin-producing capacity in patients with type 1 diabetes results in significantly better blood sugar control and reduces the risk of diabetes-related complications by more than 60 percent.

Type 1 diabetes is a chronic disease that can lead to serious complications involving considerable suffering for both patients and their family members. The disease means life-long treatment with insulin with several injections per day. It's important that the insulin dosage is neither too high nor too low, in order to keep blood sugar levels as normal as possible. Hyperglycemia (high blood sugar) and hypoglycemia (low blood

sugar) are serious and sometimes life-threatening acute complications of insulin-treated type 1 diabetes. Late complications of diabetes, which are caused by fluctuating blood sugar levels over a long period, include cardiovascular disease, leg ulcers, retinopathy and kidney damage.

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Diamyd Medical is a Swedish biopharmaceutical company focusing on development of pharmaceuticals for treatment of autoimmune diabetes and its complications. The company's most advanced project is the GAD-based drug Diamyd® for type 1 diabetes for which Phase III trials are ongoing in both the US and Europe. Furthermore, the company has started clinical studies within chronic pain, using its Nerve Targeting Drug Delivery System (NTDDS). The company has also out-licensed the use of GAD for the treatment of Parkinson's disease.

Diamyd Medical has offices in Sweden and in the US. The share is quoted on the OMX Stockholm Nordic Exchange (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available on the company's web site: <a href="https://www.diamyd.com">www.diamyd.com</a>.

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