



Press Release, March 23, 2010

## **Diamyd granted Orphan Drug Designation in the US**

*The FDA has granted Orphan Drug Designation of Diamyd Medical's lead drug candidate Diamyd®. Orphan drugs qualify for seven years of market exclusivity from the date of US marketing approval, tax credits for clinical research and a waiver for FDA user fees.*

"This is extremely good news that we finally received today", says **Elisabeth Lindner**, CEO and President of Diamyd Medical. "The granted Orphan Designation confirms the unmet medical need and might speed up the process to get the product available for children with diabetes. It may also give us extended market exclusivity in the US."

Orphan Drugs qualify for several incentives including a seven-year period of market exclusivity in the US, beginning on the date of marketing approval by the FDA. Other potential benefits are tax credits for clinical research, waiver of FDA user fees, study design assistance, and potential funding for clinical studies. Historically, the approval time for Orphan Drugs as a group has been considerably shorter than the approval time for other drugs.

Orphan Drug Designation can be granted for drugs under development for the treatment, prevention or diagnosis of a rare disease or condition. A rare disease is defined in the US as a disease affecting less than 200,000 residents.

The Orphan Drug Designation is granted for rhGAD65, the active ingredient of Diamyd®, for the treatment of type 1 diabetes with residual beta cell function.

Diamyd Medical is conducting a global Phase III clinical program to investigate whether Diamyd® can halt or slow the autoimmune destruction of insulin producing beta cells in type 1 diabetes, preserving the body's own ability to control blood sugar levels. The US study, DiaPrevent, is still enrolling patients. An improved blood sugar control reduces the risk for both acute and long-term diabetes complications. Diamyd® has been shown, in Phase II studies, to preserve the remaining beta cell function in children and adolescents recently diagnosed with type 1 diabetes.

More information about the DiaPrevent diabetes research study can be found at [www.diaprevent.com](http://www.diaprevent.com) and at [www.diaprevent.diamyd.com](http://www.diaprevent.diamyd.com).

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**About Diamyd Medical**

Diamyd Medical is a Swedish diabetes company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and its complications. The company's most advanced project is the GAD-based drug Diamyd® for type 1 diabetes. Phase III trials for this drug are in progress in both Europe and the US. In addition, the company has initiated clinical studies in the US in the area of 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. The company currently has three clinical-phase products.

Diamyd Medical has offices in Sweden and in the US. Shares are listed on Nasdaq OMX in Stockholm (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink OTC Markets and the Bank of New York Mellon (PAL). Further information is available on the company's website: [www.diamyd.com](http://www.diamyd.com).

*This information is disclosed in accordance with the Swedish Securities Markets Act, the Swedish Financial Instruments Trading Act, or the requirements stated in the listing agreements.*

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