



Press Release, June 8, 2009

## **Diamyd® Phase III study approved for younger patients in the US**

*Diamyd Medical reported today that the company has received approval from the US Food and Drug Administration, FDA, to include children with type 1 diabetes from 10 years of age in the company's Phase III study with the diabetes vaccine Diamyd®.*

Diamyd Medical is conducting two parallel Phase III studies, one in Europe and one in USA, comprising a total of 640 patients. The objective of the studies is to evaluate the ability of the Diamyd® vaccine to halt or delay the autoimmune attack on the body's insulin producing cells, thereby preserving the body's own ability to produce insulin in children and adolescents with recent-onset type 1 diabetes.

The European study, which is conducted in nine countries, is approved for patients between 10 and 20 years of age, whilst the US study so far has been approved only for patients 16 to 20 years, an age group with few recent-onset type 1 diabetes patients. The company is, with the new approval, allowed to begin enrollment of children from 10 years of age in the US Phase III study.

- This is a big step forward giving us the opportunity to accelerate patient recruitment in the US, says **Elisabeth Lindner**, President and CEO of Diamyd Medical. We are pleased that the approval comes now in connection with the world's largest diabetes conference, the ADA's 69th Scientific Sessions, which is currently ongoing in New Orleans.

The company will now, in pace with Institutional Review Board (IRB) approvals in USA, increase the number of American pediatric clinics in the study. The application for market approval is, as before, planned for spring 2011.

Diamyd Medical is represented at both #2431 at the ADA's 69th Scientific Sessions in New Orleans, USA.

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### **About Diamyd Medical**

Diamyd Medical is a Swedish biopharmaceutical 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 started 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 has currently three clinical-phase products.

Diamyd Medical has offices in Sweden and in the US. Shares are listed on the Nasdaq OMX 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 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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