

Press Release, June 1, 2011

# Diamyd regains control of diabetes therapy

Diamyd Medical AB announces it has regained control of the diabetes therapy Diamyd<sup>®</sup> following Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) election to terminate the agreement the two companies signed in June 2010 to develop and commercialize Diamyd<sup>®</sup>.

In June 2010, Diamyd Medical AB and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), a Johnson & Johnson company, signed an agreement to develop and commercialize the GAD65-based therapy Diamyd<sup>®</sup>, for the treatment and prevention of type 1 diabetes and associated conditions. Under the agreement Diamyd Medical received a non-refundable upfront payment of USD 45 million and the parties began sharing the costs for the development program equally. Following termination of the agreement by OMJPI all rights regarding Diamyd<sup>®</sup> and the active substance GAD65 are returned to Diamyd Medical.

"We have thoroughly enjoyed working with Ortho-McNeil-Janssen Pharmaceuticals, Inc. and we hope to have more opportunities for cooperation in the future," says Peter Zerhouni, Acting President and CEO of Diamyd Medical. "With all the rights to returned to us we are free to decide on how to extract the most value from GAD65 going forward."

The termination of the agreement follows the evaluation of the results of a European Phase III study with Diamyd<sup>®</sup> reported on May 9. The study did not meet the primary efficacy endpoint of preserving beta cell function at 15 months in patients newly diagnosed with type 1 diabetes, although a small positive effect was seen. Diamyd<sup>®</sup> was well tolerated as demonstrated by a similar number of adverse events in the Diamyd<sup>®</sup> treated groups as well as in the placebo treated group. Detailed results will be presented at the American Diabetes Association's 71st Scientific Sessions in San Diego, CA, USA, June 24-28, 2011.

An ongoing parallel US Phase III study, DiaPrevent, was fully enrolled in December 2010, and results are expected in the summer of 2012. In addition, the research consortium Type 1 Diabetes TrialNet is conducting a Phase II trial with Diamyd<sup>®</sup> in the US and Canada with similar design. Another externally funded and researcher-initiated Phase II study with Diamyd<sup>®</sup> is in progress aiming to prevent type 1 diabetes from developing in high risk subjects.

Apart from the diabetes therapy Diamyd<sup>®</sup> the Company's portfolio of development projects consist of several drug candidates in clinical and preclinical phases that use the Company's patented NTDDS platform (Nerve Targeting Drug Delivery System) for the administration of drugs directly to the nervous system.

The rights to the application of the GAD65 gene in the treatment of Parkinson's disease have been out-licensed on a non-exclusive basis to the American company Neurologix, Inc., which recently presented Phase II data on their GAD-based drug candidate NLX-P101 confirming sustained, positive long-term efficacy in Parkinson patients.

Besides the portfolio of patented technological platforms and development projects, Diamyd Medical has holdings in Protein Sciences Corporation (US) and Mercodia AB (Sweden).

The Company's liquid assets amounted to SEK 474 million as of February 28, 2011.

## For more information, please contact:

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### About the diabetes therapy Diamyd<sup>®</sup>

Diamyd<sup>®</sup> is an antigen-based diabetes therapy under development. The active substance in Diamyd<sup>®</sup> is the human protein GAD65 (Glutamic acid decarboxylase isoform 65 kDa). The development has been ongoing since 1994 when Diamyd Medical signed an exclusive license to patents and patent applications related to the GAD65-molecule with the University of California, Los Angeles (UCLA).

The purpose of the therapy is to prevent, delay, or stop the autoimmune attack on beta cells in type 1 diabetes and other forms of autoimmune diabetes, thereby preserving the body's capacity to regulate blood sugar. This reduces the risk for both acute and long term diabetes complications significantly. A Phase II study of 70 children and adolescents with type 1 diabetes published in The New England Journal of Medicine in 2008 showed that Diamyd<sup>®</sup> significantly slowed the progression of the disease in subjects treated within 18 months of being diagnosed with type 1 diabetes.

### **About Diamyd Medical**

Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and pain. The Diabetes business area consists of the antigen-based drug candidate Diamyd<sup>®</sup> for the treatment and prevention of autoimmune diabetes. The Pain business area consists of development projects that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system to treat chronic pain. A Phase II study of the candidate drug NP2 Enkephalin for cancer pain is ongoing in the US.

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: <u>www.diamyd.com</u>.

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.

#### **Diamyd Medical AB (publ.)**

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