



## **DIAMYD RECEIVES FDA APPROVAL TO INITIATE CLINICAL STUDY IN CHRONIC PAIN**

***Press Release, Stockholm, Sweden, and Pittsburgh, PA, USA, February 15, 2008 – Diamyd Medical AB (www.omxgroup.com, ticker: DIAM B; www.otcqx.com, ticker DMYDY)***

Diamyd Medical announced today that it has received approval from the U.S. FDA to initiate a Phase I study in chronic pain using NP2, the company's first drug candidate in its Nerve Targeting Drug Delivery System (NTDDS) gene therapy platform.

NP2, developed by the company's U.S. subsidiary, Diamyd, Inc., in Pittsburgh, produces enkephalin directly in sensory neurons to block pain signals before they are transmitted through the spinal cord to the brain. Blocking pain with a locally-targeted therapeutic in this fashion may reduce or eliminate the need for conventional systemic pain treatment and thereby avoid associated side effects.

"The quick and successful approval of the NP2 IND by the FDA is a great milestone for the company", said Michael Christini, President of Diamyd, Inc. "We have now established a regulatory foundation upon which we can advance NP2 through the clinic and which can be easily replicated to benefit our other NTDDS products such as GAD for treatment of neuropathic pain. The NTDDS platform provides a whole new mechanism for therapeutic delivery of drugs to the nervous system and we have great optimism that it will have broad application to the benefit of Diamyd Medical and potential collaborators."

"We are extremely pleased with the very favorable review the FDA has given our IND filings for both the Diamyd<sup>®</sup> GAD diabetes drug and the NP2 chronic pain product", stated Elisabeth Lindner, CEO of Diamyd Medical. "This demonstrates that Diamyd Medical now has a strong team in place that can advance both early and late stage products into the clinic which will pay dividends as our pipeline continues to grow and build shareholder value. We can now expect both trials to start according to plan."

The Phase I clinical trial will be conducted at the University of Michigan in Ann Arbor. Dr. David Fink, Professor and Chair of the Department of Neurology, at the University of Michigan will be the principal investigator. The trial will be designed as a dose-escalation study to test the safety of NP2. In total 12 patients who suffer from severe cancer-related pain are planned to be enrolled with the option to expand the trial to enroll up to 24 patients pending review of initial results.

### **About Diamyd Medical**

Diamyd Medical is a biopharmaceutical company developing treatments for diabetes and its complications. The company's furthest developed project is the GAD-based drug Diamyd<sup>®</sup> for autoimmune diabetes for which Phase III studies are planned. Diamyd<sup>®</sup> has demonstrated significant and positive results in Phase II clinical trials in Sweden.

GAD65, a major autoantigen in autoimmune diabetes, is the active substance in Diamyd. GAD65 is also an enzyme that converts the excitatory neurotransmitter glutamate to the inhibitory transmitter GABA. In this context, GAD may have an important role not only in diabetes but also in several central nervous system-related diseases. Diamyd Medical has an exclusive worldwide license from the University of California at Los Angeles regarding the therapeutic use of the GAD65 gene.

Diamyd Medical has sublicensed its UCLA GAD Composition of Matter license to Neurologix, Inc. in Fort Lee, New Jersey for treatment of Parkinson's disease.

Other projects comprise drug development within therapeutic gene transfer using the exclusively licensed and patent protected Nerve Targeting Drug Delivery System (NTDDS). The company's lead NTDDS projects include enkephalin and GAD for chronic pain, e.g., diabetes pain or cancer pain.

Diamyd Medical has offices in Stockholm, Sweden and Pittsburgh, PA. The Diamyd Medical share is quoted on the Stockholm Nordic Exchange in Sweden (NOMX ticker: DIAM B) and on the OTCQX-list in the United States (ticker: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available at [www.diamyd.com](http://www.diamyd.com).

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