



Press Release, January 17, 2011

## **Diamyd Starts Phase II Study in Cancer Pain**

*Diamyd has dosed the first subject in a Phase II clinical trial in the United States evaluating the ability of the candidate drug NP2 Enkephalin to reduce cancer pain.*

Diamyd's Phase II clinical trial with the candidate drug NP2 Enkephalin will recruit approximately 32 subjects with severe cancer pain and follow their pain scores and concomitant opioid pain medication usage. It is a multi-center, randomized, double-blind, placebo controlled study designed to provide a statistical evaluation of pain relief. The trial has a four week double-blind main study period and following this period, all patients will be offered up to two additional doses of active NP2 Enkephalin in an open label study extension. The open label study extension will measure pain scores following repeat dosing as well as provide additional safety evaluations.

"Based on the encouraging results of the Phase I trial investigating NP2 Enkephalin as a potential therapy for chronic pain, Diamyd has been able to rapidly initiate this new study in cancer patients with chronic severe pain", states Darren Wolfe, CEO of Diamyd Inc., the US subsidiary of Diamyd Medical.

Diamyd has previously announced that substantial and sustained reduction in pain scores were reported in its Phase I clinical trial intended to test the safety of NP2 Enkephalin and the Company's Nerve Targeting Drug Delivery System (NTDDS) in patients with intractable pain due to cancer. No treatment related Serious Adverse Events have been observed in the Phase I study to date.

"The serious unmet medical need of efficient pain relief is a strong driver for our team to continue development of NP2 Enkephalin and the NTDDS platform", says Elisabeth Lindner, CEO and President of Diamyd Medical. "With the Phase II study Diamyd intends to show proof-of-concept for the NP2 Enkephalin treatment, which is the furthest advanced project in our portfolio of pain-relieving drug candidates based on the proprietary NTDDS platform."

NTDDS represents a new class of pharmaceutical products that delivers gene-based drugs directly to nerve cells, providing a direct effect in the cells targeted by the treatment. The drug candidate NP2 Enkephalin has been engineered to deliver the human Enkephalin gene, which naturally produces opioid peptides involved in pain control, directly to the site of pain in the peripheral nervous system.

"In preclinical studies, vector-mediated gene delivery has been shown to be effective in models of inflammatory pain, including arthritis pain, and pain from nerve damage due to injury or diabetes in addition to cancer pain. This Phase II clinical trial is an incredibly important step not only for cancer pain, but for establishing proof-of-principle in patients for this approach to treating pain", says David Fink, MD, Robert Brear Professor and chair of the department of neurology at the University of Michigan, and lead investigator of the trial.

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**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® for the treatment and prevention of autoimmune diabetes. Phase III studies of Diamyd® are currently in progress in Europe and the US. In 2010 the Company signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., for the development and commercialization of Diamyd®. 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.

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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