



Press Release, April 11, 2011

## **Diamyd results from Phase I clinical trial in cancer pain published in Annals of Neurology**

*Diamyd Medical's Phase I clinical trial results evaluating the safety and efficacy of the candidate drug NP2 Enkephalin to treat intractable cancer pain has been published in the medical journal Annals of Neurology.*

The publication, entitled "Gene Therapy for Pain: Results of a Phase I Clinical Trial" details the results of Diamyd's Phase I dose-escalation clinical trial of NP2 Enkephalin through the four month evaluation period. The paper is accepted for publication in the medical journal Annals of Neurology and is available online as a pre-print. The study was designed to provide an assessment of the safety of three different doses of NP2 Enkephalin and also to investigate efficacy measurements of pain relief in subjects suffering from chronic pain due to malignancy. Substantial and sustained pain relief was noted in the middle and high dose cohorts in both pain measurement methods used in the study; the numeric rating scale (NRS) which is a scale of 0-10 and the Short Form McGill Pain Questionnaire (SF-MPQ) which is a quantitative compilation of 15 descriptive pain measures. In the highest dose cohort, an ~80% decrease in the combined average weekly NRS scores was observed over the first four weeks.

"A publication of the results from our first clinical trial with NP2 Enkephalin in Annals of Neurology underscores the interest from the medical community for our pioneering approach to treat pain", states co-author Darren Wolfe, President of Diamyd Inc., the US subsidiary of Diamyd Medical, responsible for the development of the proprietary Nerve Targeting Drug Delivery System.

Ten subjects with moderate to severe cancer pain, despite treatment with the maximum tolerated dosages of standard opioid medications, were enrolled into the study. Safety evaluation of patients through four months indicates that delivery into the skin of NP2 Enkephalin is well tolerated with no observed treatment related serious adverse events.

Results are to be confirmed in an ongoing Phase II, randomized, double blind, placebo controlled clinical trial of NP2 Enkephalin in 32 patients with severe intractable cancer pain at approximately 10 clinical sites in the US. This study is currently enrolling participants.

The results of the NP2 Enkephalin Phase I clinical trial will also be presented at the 63rd Annual Meeting of the American Academy of Neurology, 9th - 16th of April 2011 in Honolulu, Hawaii, USA.

The Nerve Targeting Drug Delivery System (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 NTDDS based candidate drug NP2 Enkephalin has been engineered to deliver the human Enkephalin gene, which naturally produces opioid peptides involved in pain control.

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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. 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: [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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