



Press Release, September 12, 2011

## **Diamyd awarded three million dollar grant and expands the NTDDS portfolio**

*Diamyd Medical AB with collaborators has received a three million dollar grant from the US National Institutes of Health to develop the Company's patented Nerve Targeting Drug Delivery System (NTDDS) for prevention of Chemotherapy Induced Peripheral Neuropathy. The grant allows Diamyd to expand the NTDDS technology to also target neuropathy, in addition to the Company's development portfolio for the treatment of pain.*

The three-year grant funds the development of a NTDDS-based drug candidate, engineered to deliver a neurotrophic factor to nerve cells. It is hoped that use of NTDDS to deliver such a neurotrophic factor to cancer patients prior to initiating chemotherapy will prevent peripheral neuropathy, which is a common side effect of chemotherapy. Typical symptoms of peripheral neuropathy are numbness, pain, tingling, or burning sensations in hands and feet.

"Expanding the application of the NTDDS technology from pain therapy to include the treatment and prevention of neuropathy is something we have foreseen for a long time," says Peter Zerhouni, President and CEO of Diamyd Medical. "With the non-dilutive funding provided by the grant we can take this step earlier than anticipated."

The grant covers the costs for advancement of the new drug candidate through preclinical efficacy, toxicology and biodistribution studies, manufacturing and filing of an Investigational New Drug application with the US Food and Drug Administration (FDA). The grant is awarded to David Fink, M.D., Professor and Chairman, Department of Neurology at the University of Michigan, and Darren Wolfe, Ph.D., President of Diamyd, Inc., as principle investigators.

"Building off our clinical development of NTDDS for the treatment of pain, this grant will allow us to accelerate the critical steps in translating our preclinical findings in Chemotherapy Induced Peripheral Neuropathy into human therapy," says Darren Wolfe. "Chemotherapy Induced Peripheral Neuropathy represents an important unmet medical need that we have identified as an attractive market opportunity for our unique NTDDS technology."

"Chemotherapeutics are invaluable tools in the fight against cancer," says Dr. David Fink, a long-term collaborator doing research with Diamyd Medical's NTDDS technology. "Unfortunately, they also produce serious side effects, such as peripheral neuropathy, which often prevents administration of higher more effective chemotherapy doses. Treatment with NTDDS delivering a neurotrophic factor may not only prevent the development of Chemotherapy Induced Peripheral Neuropathy, but may also allow more effective chemotherapy doses to be administered to the patient."

Neurotrophic factors are a class of small proteins that were originally identified by their role in brain development and their ability to prevent specific cell death of nerve cells during development. In the adult nervous system, neurotrophic factors promote the survival, growth, connectivity, and proper function of nerve cells and aid in recovery of nerve function following injury. Targeted delivery of neurotrophic factors to nerve cells could lead to treatments for central and peripheral neurodegenerative diseases.

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### **About NTDDS**

Diamyd Medical's portfolio of drug candidates for the treatment of pain comprises the drug candidates NP2 Enkephalin, NG2 GAD and NE2 Endomorphin. They are based on the Company's patented NTDDS platform (Nerve Targeting Drug Delivery System) and developed for the treatment of chronic pain, such as cancer pain and diabetes pain. NTDDS delivers gene-based drugs directly to nerve cells, providing a local effect in the cells targeted by the treatment. NTDDS also has potential to be used for treating diseases of the peripheral and central nervous system such as peripheral neuropathy, erectile dysfunction (impotence), neurodegenerative diseases and cancer.

NP2 Enkephalin produces the opioid enkephalin locally for the treatment of pain and is the furthest developed drug candidate in the portfolio. NP2 Enkephalin has been evaluated in a clinical Phase I study for treatment of chronic cancer pain and is now being tested further in a Phase II study.

The Phase I study with NP2 Enkephalin was designed as an open label, dose-escalation study in patients with intractable pain due to malignant cancer. Although the study was not primarily conducted to study efficacy, substantial and sustained pain relief was observed. No treatment related serious adverse events have been reported by any participant in the study. The Phase I study has laid the groundwork for future studies with other drug candidates that use NTDDS to treat other diseases and conditions.

In the ongoing Phase II trial with NP2 Enkephalin, the study subjects' pain scores and their concomitant pain medication usage are being followed. The study is a multicenter, placebo-controlled clinical trial designed to enable a statistical evaluation of pain relief and will recruit approximately 32 subjects with severe cancer pain. The study includes a four-week double-blind study period, after which all patients will be offered up to two additional doses of active NP2 Enkephalin in an open label study extension.

The next NTDDS-based drug candidate in Diamyd Medical's pain portfolio is NG2 GAD for the treatment of diabetes pain. NG2 GAD also has potential to be used for the treatment of several other diseases.

### **About Diamyd Medical**

Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of pain and autoimmune diabetes. The portfolio of development projects for the treatment of chronic pain uses the Company's patented NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system. The development project within the area of diabetes consists of the protein GAD65 for the treatment and prevention of autoimmune diabetes.

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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