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Diamyd Medical's Phase II study in cancer pain fully recruited

The last study participant has been recruited to Diamyd Medical's Phase II study in which cancer pain is treated with the drug candidate NP2 Enkephalin. The study is thus fully enrolled and results are expected to be reported in five to seven weeks.

The purpose of the Phase II study is to evaluate NP2 Enkephalin for the treatment of severe and chronic cancer pain. It is the first sizeable and placebo-controlled clinical trial of a drug candidate based on Diamyd Medical's patented Nerve Targeting Drug Delivery System, a unique technology for delivery of therapeutics directly to the nervous system.

"After an intense effort to recruit the last few subjects, the Phase II study is now fully enrolled and we will soon be able to evaluate whether our unique concept to treat severe pain works also in this larger study," says Peter Zerhouni, President and CEO of Diamyd Medical. "With the study results we hope to establish proof of principle for this innovative method to treat pain by delivering therapeutics directly to the nervous system. If the concept proves successful, it will provide many new opportunities to treat pain and other medical problems in the nervous system for which there are currently no effective treatments available."

The Phase II study comprises approximately 32 subjects with severe cancer pain and is being conducted at 18 clinics in the United States. It is a multicenter, placebo controlled, double-blind and randomized study. There is a four-week, double-blind study period where the subjects' pain scores are being monitored and recorded. The first results from the study are expected to be reported in five to seven weeks. After the four week blinded study period all patients are offered up to two doses of active NP2 Enkephalin in an unblinded study extension. The follow-up will collect pain scores following repeat dosing as well as provide additional safety data.

NP2 Enkephalin is the furthest advanced drug candidate within the NTDDS platform and delivers the natural painkilling substance enkephalin directly to the nervous system for the treatment of pain. Substantial and sustained pain relief has previously been observed in a Phase I study with the purpose to evaluate the safety of NP2 Enkephalin and the NTDDS platform. The study was designed as a dose-escalation study with three different doses, comprising ten subjects with medium to severe cancer pain refractory to maximal doses of pain medication. The results of the study were presented in the autumn of 2010. No serious side-effects related to the treatment have been reported by any of the participants in the study.

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About the NTDDS platform

Diamyd Medical's Nerve Targeting Drug Delivery System (NTDDS) is an innovative technology for the delivery of therapeutics directly to the nervous system and forms the basis of the Company's development projects within pain and neuropathy. The NTDDS technology aims to provide a local effect in the parts of the body where the treatment is targeted without affecting the rest of the body.

The NTDDS platform comprises three drug candidates for the treatment of various forms of chronic pain; NP2 Enkephalin, NG2 GAD, NE2 Endomorphin and one drug candidate for the prevention of chemotherapy induced peripheral neuropathy, NN1 Neurotrophin.

Diamyd Medical's NTDDS-based drug candidates consist of a vector which carries a gene for a therapeutic substance, e.g., a painkilling substance. The drug is injected into the skin, where the vector and the gene are taken up by nerve endings and then transported along the body's peripheral nerve pathways to nerve cell bodies

that lie just outside the spinal cord. Here the nerve cell's own processes are being used to continuously produce the therapeutic substance with the gene as template.

The NTDDS technology is expected to have several advantages over established therapies. Since NTDDS is gene-based, a single dose can provide a relatively long-term therapeutic effect that may last several weeks to months. As the treatment acts locally, a very low amount of the drug may be enough to achieve the desired effect. Furthermore, systemic drug exposure is limited, a fact that may significantly reduce the risk of side effects.

The technology has a wide potential and may be used for the treatment of several different diseases and symptoms in the peripheral and central nervous system such as chronic pain, neuropathy (nerve damage), cancer and neurodegenerative diseases. Research and development on the NTDDS platform is primarily carried out by the subsidiary Diamyd, Inc. located in Pittsburgh, USA.

About Diamyd Medical

Diamyd Medical is a Swedish biotech company focusing on the development of pharmaceuticals for the treatment of pain, neuropathy and diabetes. The development projects for the treatment of chronic pain and neuropathy uses the Company's patented NTDDS (Nerve Targeting Drug Delivery System) platform to administer therapeutic agents 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 also has holdings in the companies Protein Sciences Corporation (USA) and Mercodia AB (Sweden).

Diamyd Medical has offices in Sweden and in the US. Shares are listed on Nasdaq OMX (segment Small Cap) 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.

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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