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Medexus Pharmaceuticals Announces Deal for Gleolan in the United States

Medexus has acquired exclusive rights to commercialize Gleolan in the United States, complementing Medexus's existing rights to Gleolan in Canada

Gleolan is an optical imaging agent currently indicated in the United States in patients with glioma as an adjunct for the visualization of malignant tissue or tumor tissue during surgery

Gleolan generated \$3-4 million U.S. net sales in the fourth calendar quarter of 2021

TORONTO and CHICAGO, March 01, 2022 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals (**Medexus**) (TSX: MDP) (OTCQX: MEDXF) is pleased to announce that its U.S. subsidiary, Medexus Pharma (**Medexus US**), has acquired the exclusive right to commercialize Gleolan in the United States from NX Development Corp. (**NXDC**), the U.S. subsidiary of photonamic GmbH & Co. (**Photonamic**). This transaction extends Medexus's strong relationship with Photonamic and complements Medexus's existing commercialization rights to Gleolan in Canada, where Medexus recently launched the product. Using information provided by NXDC, Medexus estimates that Gleolan generated U.S. net sales of \$3 million to \$4 million in the fourth calendar quarter of 2021. Based on Medexus's evaluation of Gleolan's effectiveness, Medexus is confident in Gleolan's prospects in both Canada and the United States, and expects strong sales and institutional uptake in both markets. Medexus and NXDC plan to work together closely to ensure a seamless transition for existing customers.

Under the terms of Medexus's new license, supply, and distribution agreement, Medexus will commercialize Gleolan in the United States and will pay NXDC annual royalty payments (tiered based on net sales relative to an annual minimum baseline and net of supply price paid) and periodic low- to mid-single-digit-million dollar milestone payments (including an upfront payment, two payments triggered by passage of time, and three payments triggered by achievement of net sales thresholds). NXDC will supply Gleolan to Medexus and will remain the sponsor of the new drug application for Gleolan on file with the U.S. Food and Drug Administration (**FDA**). This transaction will allow NXDC, as sponsor, to continue the company's important research and development activities, including pursuit of additional indications for Gleolan. Medexus US's exclusive commercialization rights extend to one additional indication, meningioma, with the opportunity to negotiate commercialization rights to future indications. The initial term of the parties' arrangement will extend through and including March 31, 2028 with successive two-year extension terms thereafter.

"We are thrilled to license Gleolan in the United States and continue to drive our business forward," said Ken d'Entremont, Medexus's chief executive officer. "We believe Gleolan has a bright future and testing is currently underway for its use for meningioma, which would be a

new indication.” Mr d’Entremont then continued, “This product fits extremely well into our portfolio. We are already very familiar with Gleolan given our successful launch of the product in Canada early last year. Extending our Gleolan distribution rights into the United States will allow us to continue developing our U.S. operations. We expect this product will both grow our U.S. revenues and allow us to put in place an infrastructure that will also support our U.S. launch of Treosulfan planned for later this year, assuming FDA approvals have been obtained.”

(Note: Dollar figures in this press release are expressed in U.S. dollars unless otherwise indicated.)

About Gleolan

Gleolan (aminolevulinic acid hydrochloride or ALA HCl) is an FDA-approved optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery. The FDA has granted Gleolan orphan drug designation through June 2024.

Gleolan makes high-grade gliomas (malignant, rapidly progressive brain tumors) fluoresce under a particular form of fluorescent blue light. Gleolan is a powder and is administered to patients as an oral solution. After administration, when the brain is exposed to blue light during surgery, areas within the tumor glow pink or red in contrast to healthy brain tissue which appears blue. This assists neurosurgeons in better visualizing these gliomas to facilitate more complete removal.

Surgeons using fluorescence-guided surgery with Gleolan demonstrated significant improvement in extent of resection when compared to procedures using white light. NXDC estimates that to date ALA HCl has been used in over 42 countries for over 100,000 patients worldwide.

The American Society of Clinical Oncology estimated that in 2021 approximately 24,500 adults in the United States would be diagnosed with primary cancerous tumors of the brain and spinal cord. According to the American Association of Neurological Surgeons, glioblastoma is the most common malignant central nervous system tumor, accounting for 47.7% of all diagnosed cases, and has an incidence of 3.21 per 100,000 population.

About Medexus

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform and a portfolio of proven best-in-class products. Our current focus is on the therapeutic areas of hematology, auto-immune diseases, and allergy. We continue to build a highly differentiated company with a growing portfolio of innovative and high-value orphan and rare disease products that will underpin our growth for the next decade.

Our current leading products are Rasuvo™ and Metoject®, a unique formulation of methotrexate (auto-pen and pre-filled syringe) designed to treat rheumatoid arthritis and other auto-immune diseases; IXINITY®, an intravenous recombinant factor IX therapeutic for use in patients 12 years of age or older with Hemophilia B (a hereditary bleeding disorder characterized by a deficiency of clotting factor IX in the blood, which is necessary to control

bleeding); and Rupall®, an innovative prescription allergy medication with a unique mode of action.

We have also licensed Treosulfan, a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, for commercialization in the United States and Canada. Treosulfan was approved by Health Canada in June 2021 and is marketed in Canada as Trecondyv®. Treosulfan is currently under review by the U.S. Food and Drug Administration.

Our mission is to provide the best healthcare products to healthcare professionals and patients. We strive to deliver on this mission by acting on our core values: Quality, Innovation, Customer Service, and Collaboration.

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Forward-Looking Statements

Certain statements made in this press release contain forward-looking information within the meaning of applicable securities laws (**forward-looking statements**). The words “anticipates”, “believes”, “expects”, “will”, “plans”, “potential”, and similar words or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Specific forward-looking statements contained in this news release include, but are not limited to, statements regarding potential future annual net sales, potential future indications for Gleolan, and the timing of Treosulfan launch in the United States and related FDA approval, among others. These statements are based on factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, including assumptions based on historical trends, current conditions and expected future developments. Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. Medexus cautions that although it

is believed that the assumptions are reasonable in the circumstances, these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in the forward-looking statements. Material risk factors include those set out in Medexus's materials filed with the Canadian securities regulatory authorities from time to time, including Medexus's most recent annual information form and management's discussion and analysis; future capital requirements and dilution; intellectual property protection and infringement risks; competition (including potential for generic competition); reliance on key management personnel; Medexus's ability to implement its business plan; Medexus's ability to leverage its U.S. and Canadian infrastructure to promote additional growth; regulatory approval by relevant health authorities, including the FDA; product reimbursement by third party payers; litigation or expiry with respect to patents or other intellectual property rights; litigation risk; stock price volatility; government regulation; and potential third party claims. Given these risks, undue reliance should not be placed on these forward-looking statements, which are made only as of the date hereof. Other than as specifically required by law, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.



Source: Medexus Pharmaceuticals Inc