September 10, 2020

# Medexus Reports Health Canada Approval of Gleolan® (5-ALA) for Use in Guided Surgical Resection of High-Grade Gliomas

TORONTO and CHICAGO and MONTREAL, Sept. 10, 2020 (GLOBE NEWSWIRE) -- **Medexus Pharmaceuticals Inc. (the "Company" or "Medexus") (TSXV: MDP, OTCQX: MEDXF)** today announces that on September 9, 2020, it received a Notice of Compliance from Health Canada granting approval for the marketing of Gleolan® in Canada. Gleolan® is a 5-aminolevulinic acid hydrochloride (5-ALA) powder for oral solution, and is indicated as an adjunct for the visualization of malignant tissue during surgery in patients with Grades III or IV gliomas (suspected on preoperative imaging) as classified by the World Health Organization (WHO).

"Every day in Canada it is estimated that 27 new primary brain tumours will be diagnosed. With limited treatment options, new advancements that assist neurosurgeons in successfully removing brain tumours bring hope to patients facing this often devastating disease," says Susan Marshall, CEO for Brain Tumour Foundation of Canada, which supports the 55,000 people in Canada affected by brain tumours.

Gleolan® is an imaging agent that makes high-grade gliomas (malignant, rapidly progressive brain tumours) fluoresce under blue light, assisting neurosurgeons to better visualize these gliomas for more complete removal. After administration, areas within the tumour glow pink or red, and healthy brain tissue appears blue when exposed to a special blue light during surgery. There are currently no other optical imaging agents approved in Canada for the purpose of visualization of malignant tissue during glioma surgery.

A pivotal Phase III study, published in The Lancet Oncology Medical Journal, has shown that use of Gleolan® during brain tumour surgery has nearly doubled the rate of achieving a complete resection of the tumour, which in turn has resulted in a doubling of the number of patients without progression of their brain cancer six months after surgery.[1] The study reported complete resection of malignant brain tumour tissue in 65% of patients receiving Gleolan® compared to 36% of patients in the study's control arm (difference between groups 29% [95% CI 17-40], p<0·0001). Six-month progression-free survival was achieved in 41% of patients receiving Gleolan® compared to 21% of patients who were operated on without the use of the drug (difference between groups 20% [95% CI 9·1–30·7], p=0·0003).[1]

Mr. Ulrich Kosciessa, Chief Executive Officer of photonamic GmbH & Co. KG, noted, "Gleolan® is already approved for use in more than 40 countries, including Germany, United States, United Kingdom, Japan, South Korea, Australia and New Zealand, and the approval in Canada marks another milestone in the global development of the drug." Mr. Kosciessa continued, "We are delighted that Medexus has been able to successfully achieve an

approval from Health Canada and that Gleolan® will now be available for Glioblastoma multiforme patients in Canada. More than 80,000 patients globally have already benefited from the use of Gleolan® in brain tumour resection."

Health Canada had previously granted Medexus authorization to distribute Gleolan® in Canada under the Special Access Programme, which provides healthcare practitioners with access to non-marketed drugs to treat patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. In March 2020, the Quality business unit at Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommended publicly funding Gleolan® for guiding maximal surgical resection of high-grade gliomas, which was conditional on Health Canada approval of the technology. The Company is awaiting final funding approval from the Ontario Ministry of Health.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "We are very pleased to have received regulatory approval from Health Canada allowing Gleolan® to be commercially available in Canada for use in fluorescence-guided brain cancer neurosurgery. Thanks to the collaboration and ongoing support from our partners at photonamic, in obtaining the full registration of Gleolan®, we are now able to access a much larger group of adult patients suffering from high-grade gliomas in Canada. The incidence of glioblastoma is 4 per 100,000 people in Canada and about 1,000 Canadians will be diagnosed with glioblastoma every year, according to the Brain Tumor Registry of Canada. The feedback from the medical community has been extremely positive, and I'd like to acknowledge the special contribution of Dr. John Sinclair and his team from The Ottawa Hospital that have pioneered the use of Gleolan® in Canada. We expect Gleolan® will be a tremendous asset for clinicians in addressing their significant medical need for enhanced tumor visualization during surgery."

Dr. John Sinclair, Neurosurgeon and Director of Neurosurgical Oncology at The Ottawa Hospital, commented, "Using Gleolan® for complicated brain tumor surgery can lead to substantially improved outcomes for patients, while serving as a cost-effective tool for surgical resection of glioblastoma and other high grade tumours. Gleolan® enables neurosurgeons to find the ill-defined tumor margin, as achieving this in surgery is often difficult since the brain and tumor tissue appear visually similar under the typical white light microscope. This is a game-changer for neurosurgeons who are treating patients facing life threatening malignant gliomas. Gleolan® helps the surgeon to remove cancerous cells with improved accuracy and enhanced visualization of high-grade glioma tissue. This surgery technique has been practiced in other parts of the world for years and is standard in Europe. I would like to see fluorescence-guided surgery become the standard in Canada with Canadian hospitals offering patients this breakthrough treatment technology."

**About Medexus**

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform. The Company's vision is to provide the best healthcare products to healthcare professionals and patients, through our core values of Quality, Innovation, Customer Service and Teamwork. Medexus Pharmaceuticals is focused on the therapeutic areas of auto-immune disease, hematology and allergy. The Company's 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 allergy medication with a unique mode of action.

References:
1. Stummer W, Pichlmeier U, Meinel T, et al., Fluorescence-guided surgery with 5-aminovulinec acid for resection of malignant glioma: a randomised controlled multicentre phase III trial, Lancet Oncol, 2006;7:392-401

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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. The Company 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 the Company's most recent MD&A; future capital requirements and dilution; intellectual property protection and infringement risks; competition (including potential for generic competition); reliance on key management personnel; the Company's ability to implement its business plan; the Company's ability to leverage its United States and Canadian infrastructure to promote additional growth, including with respect to the infrastructure of Medexus Inc. and Medac Pharma, Inc. and the potential benefits the Company expects to derive therefrom;, regulatory approval by the Canadian health authorities; product reimbursement by third party payers; patent litigation or patent expiry; 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 apply only as of the date hereof. Other than as specifically required by law, the Company undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.




Source: Medexus Pharmaceuticals Inc