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Medexus Announces Expanded Availability of Gleolan® in Canada

TORONTO and CHICAGO and MONTREAL, Feb. 25, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "**Company**" or **"Medexus**") (TSXV: MDP) (OTCQX: MEDXF) (Frankfurt: P731) announced today that it has initiated the commercial launch of Gleolan® in Canada, which had previously only been distributed under the Health Canada Special Access Program. 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, and expanded availability of Gleolan in Canada, which assists neurosurgeons in successfully removing brain tumours, brings hope to patients facing this often devastating disease," stated 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 Gliolan 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 tumor tissue in 65% of patients receiving Gliolan 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 Gliolan 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]

Ulrich Kosciessa, CEO of photonamic, Medexus' licensing partner, noted, "Shipping the first Gleolan units to Canada last week was truly an important milestone, not only for us at photonamic and for Medexus, but most importantly for patients and neurosurgeons in the country. Many neurosurgeons have already been trained on the product by Medexus so that they can immediately start using it. Gleolan has already been used in over 100,000 cases worldwide, providing hope for patients with these certain types of brain tumours. We look forward to continuing our excellent collaboration with Medexus as Gleolan will now be

available across Canada."

Kerry Bakewell, Vice President of Specialty Markets at Medexus, commented, "According to the Brain Tumour Registry of 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. For this reason, we are extremely pleased to be able to expand the accessibility of Gleolan in Canada beyond the Health Canada Special Access Program. This allows us to provide Gleolan to more institutions and neurosurgeons, many of which have already been trained, and therefore they are educated on the product and immediate use is possible. We continue to believe that Gleolan will be a tremendous asset for clinicians in addressing their significant medical need for enhanced tumour visualization during surgery."

Dr. John Sinclair, Neurosurgeon and Director of Neurosurgical Oncology at The Ottawa Hospital, commented, "When I first read European journal articles outlining the use of 5-ALA / Gleolan, I felt strongly that this represented an innovative surgical technique that would benefit our patients diagnosed with malignant gliomas. With the support of Medexus, we have been able to bring Gleolan to Canada and help to develop its use across the country. To date I have used this technique for approximately 75 patients and have directly observed its outstanding benefits during surgery which allow for enhanced optimal safe tumour resection. This research demonstrated that surgery done with 5-ALA led to an extended length of time to tumour recurrence and improved patient outcomes in comparison to traditional "white light" surgery. Final approval from Health Canada will allow for a more readily available supply that will be of benefit to more patients and provide an excellent standard of care moving forward. We look forward to widely developing the use of Gleolan in Canada and offering patients optimal surgery for gliomas."

Health Canada had previously granted Medexus authorization to distribute Gleolan in Canada under the Special Access Program, 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.

About Medexus Pharmaceuticals Inc.

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform. From a foundation of proven best in class products we are building a highly differentiated company with a portfolio of innovative and high value orphan and rare disease products that will underpin our growth for the next decade. 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 prescription allergy medication with a unique mode of action.

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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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