

March 4, 2019

# Medexus Enters into Expanded Licensing Agreement for Gliolan® in Canada

## Prior Phase III study showed complete resection rates and doubling of 6-month progression-free survival in patients receiving Gliolan

MONTREAL, March 04, 2019 (GLOBE NEWSWIRE) -- **Medexus Pharmaceuticals Inc. (the “Company” or “Medexus”) (TSXV: MDP, OTCQB: PDDPF)** today announced that it has entered into a licensing agreement with photonamic GmbH & Co. KG (“photonamic”) for the exclusive rights to market and distribute Gliolan® in Canada, which assists neurosurgeons to better visualize and more completely remove malignant brain tumors (gliomas) by causing them to become fluorescent and glow during surgery.

Health Canada previously granted Medexus authorization to distribute Gliolan in Canada via the Special Access Program (“SAP”), 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. Under the original agreement, the Company had limited distribution rights to the product. Under the expanded license agreement, The Company now has the long-term exclusive rights to market and distribute Gliolan in Canada. Medexus plans to file for registration of Gliolan with Health Canada in 2019 and expects to receive full registration within 12 to 18 month following application.

Every day, 27 Canadians are diagnosed with a brain tumor, with the most common type of primary malignant brain tumor being glioblastoma multiforme. Brain tumors are the leading cause of solid cancer death in children under the age of 20, now surpassing acute lymphoblastic leukemia and they are the third leading cause of solid cancer death in young adults ages 20-39<sup>1</sup>.

Gliolan is given to the patient as a drink two to four hours before surgery. During surgery, a neurosurgical microscope fitted with a specialized blue operating light is used, which causes cancerous tissue to glow fluorescent pink while normal brain tissue appears blue. This provides better visualization for the surgeon while performing the surgery, which has shown to provide a more complete removal of the tumor during surgery with the use of Gliolan. Phase III studies have demonstrated complete resection rates and a doubling of 6-month progression-free survival in patients receiving Gliolan. (reference)

“We are very pleased with the addition of Gliolan to our expanding product portfolio, as we aim to execute on our vision of providing the best healthcare products to consumers and healthcare professionals across North America. The response from the medical community has been extremely positive, as evidenced by strong market uptake. This expanded, long-term exclusive agreement now provides us the opportunity to supply Gliolan in Canada, which we believe has the potential to improve patient survival. We expect Gliolan will be a tremendous asset for clinicians in addressing their significant medical need for enhanced tumor visualization during surgery,” stated Ken d’Entremont, Chief Executive Officer of Medexus.

“We are happy to have partnered with Medexus to make Gliolan available to patients in Canada. Through this collaboration, photonamic is able to further expand the accessibility of this product globally,” Ulrich Kosciessa, CEO of photonamic explained.

The Company also announces that today, it has re-filed its interim financial statements and interim MD&A for the period ended December 31, 2018, as the originally filed financial statements and MD&A, which were filed on February 25, 2019, contained incorrect figures relating to selling and administrative expenses for the period ended December 31, 2017 as a result of an administrative error. The correction was made to both the financial statements and MD&A to reflect the numbers as previously disclosed accurately in 2017. The correction in the financial statements only impacted note 9 of the financial statements and does not impact any of the amounts in the Condensed Interim Consolidated Statements of Cash Flows, Condensed Interim Consolidated Statements of Income (Loss) and Comprehensive Income (Loss), Condensed Interim Consolidated Statements of Changes in Shareholders' Equity, the Condensed Interim Consolidated Statements of Financial Position, or any of the other notes to the financial statements. No other significant changes have been made to the financial statements or MD&A.

### 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 and pediatrics. The 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; and Rupall, an innovative allergy medication with a unique mode of action.

### **About photonamic**

photonamic is a German based life science company engaged in research and development of drugs that use 5-Aminolevulinic Acid (5-ALA). As a member of the SBI group, Tokyo Japan, photonamic's parent company, SBI ALApharma, Hong Kong, is focused on developing and marketing 5-ALA based products globally. Gliolan<sup>®</sup>, as an intra-operative diagnostic drug, was launched for the visualization of brain tumors and approved by the European Medicines Agency (EMA) in 2007, as well as by the FDA in 2017 under the name Gliolan. Today, Gliolan is sold in over 40 countries worldwide.

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#### **Forward Looking Statements**

This press release contains "forward-looking information" within the meaning of applicable securities legislation. Forward-looking information includes, but is not limited to, statements with respect to future business operation, the timing of regulatory approvals, the success of certain drug therapies and results. All statements, other than of historical fact, that address activities, events or developments that the Company believes, expects or anticipates will or may occur in the future are forward-looking statements. Forward-looking statements are generally identifiable by use of the words "may", "will", "should", "continue", "expect", "anticipate", "estimate", "believe", "intend", "plan" or "project" or the negative of these words or other variations on these words or comparable terminology. Forward-looking statements are subject to a number of risks and uncertainties, many of which are beyond the Company's ability to control or predict, that may cause the actual results of the Company to differ materially from those discussed in the forward-looking statements. Factors that could cause actual results or events to differ materially from current expectations include, among other things, without limitation, the risk that the Company will not receive regulatory approvals in a timely manner or at all, the results of certain drug therapies and their impact on the Company's profitability, the Company's business plans, and other risks disclosed in the Company's public disclosure record on file with the relevant securities regulatory authorities. Although Company believes that the expectations and assumptions on which such forward-looking information is based are reasonable, undue reliance should not be placed on the forward-looking information because Company can give no assurance that they will prove to be correct. Since forward-looking information addresses future events and conditions, by its very nature they involve

inherent risks and uncertainties. The Company's actual results, performance or achievement could differ materially from those expressed in, or implied by, the forward-looking information and, accordingly, no assurance can be given that any of the events anticipated by the forward-looking information will transpire or occur, or if any of them do so, what benefits that Company will derive therefrom. Management has included the above summary of assumptions and risks related to forward-looking information provided in this press release in order to provide securityholders with a more complete perspective on the Company's future operations and such information may not be appropriate for other purposes. Readers should not place undue reliance on forward-looking statements. Readers are cautioned that the foregoing lists of factors are not exhaustive. Additional information on these and other factors that could affect the Company's operations or financial results are included in reports on file with applicable securities regulatory authorities and may be accessed through the SEDAR website ([www.sedar.com](http://www.sedar.com)). The forward-looking statements included in this news release are made as of the date of this news release and the Company does not undertake an obligation to publicly update such forward-looking statements to reflect new information, subsequent events or otherwise unless required by applicable securities legislation.

<sup>1</sup> Source: Brain Tumor Foundation of Canada (<https://www.braintumour.ca/2494/brain-tumour-facts>)



Source: Medexus Pharmaceuticals Inc