November 19, 2019

Medexus Granted Priority Review Status for Gliolan® by Health Canada

Priority review expected to significantly reduce timeline for full regulatory approval of Gliolan®

MONTREAL, Nov. 19, 2019 (GLOBE NEWSWIRE) -- **Medexus Pharmaceuticals Inc. (the "Company" or "Medexus") (TSXV: MDP, OTCQB: PDDPF)** today announced that Health Canada has granted priority review status for the New Drug Submission (NDS) for Gliolan® (5-aminolevulinic acid hydrochloride). Gliolan® is used for guiding maximal surgical resection of high-grade gliomas (malignant brain tumors) in adults. Gliolan® assists neurosurgeons to better visualize and more completely remove gliomas by causing them to become fluorescent and glow during surgery. Medexus anticipates filing the NDS in 2019 for approval to market and sell Gliolan® in Canada.

Priority Review status assigns eligible submissions a shortened review target of 180 days, in comparison to 300 days for non-priority review. Priority review status may be granted by Health Canada to an NDS intended for the treatment of serious, life-threatening or severely debilitating diseases or conditions for which there is no existing drug on the Canadian market with the same profile or where the new product represents a significant improvement in the benefit/risk profile over existing products.

Gliolan® is a diagnostic aid to facilitate maximal safe resection of high-grade gliomas (WHO grade III-IV). High-grade gliomas are malignant, rapidly progressive cancers. Glioblastoma multiforme (WHO grade IV), the most common glial tumor, accounting for approximately 80% of patients with primary malignant brain tumors, has a median survival of 12 to 15 months. There are currently no optical imaging agents approved in Canada for the purpose of visualization of malignant tissue during glioma surgery.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "Priority review for Gliolan® should significantly accelerate our path to approval and follows the recent draft recommendation for public reimbursement by Health Quality Ontario. Feedback from the medical community has been extremely positive and we are experiencing strong market uptake under the Special Access Program, even prior to full registration. Gliolan® not only improves patient outcomes but is also a cost-effective solution for high level glioblastoma patients. Once Gliolan® becomes a fully registered product, we expect it to gain much broader distribution in Canada, which represents a sizeable, underserved market opportunity."

Health Canada previously granted Medexus authorization to distribute Gliolan® 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. The Company has long-

term exclusive rights to market and distribute Gliolan® in Canada.

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 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. For additional information, please visit the Company's website: www.medexus.com.

For more information, please contact:

Ken d'Entremont, Chief Executive Officer
Medexus Pharmaceuticals Inc.
Tel.: 905-676-0003
E-mail: ken.dentremont@medexus.com

Roland Boivin, Chief Financial Officer
Medexus Pharmaceuticals Inc.
Tel.: 514-762-2626 ext. 202
E-mail: roland.boivin@medexus.com

Investor Relations (U.S.):
Crescendo Communications, LLC
Tel: +1-212-671-1020
Email: mdp@crescendo-ir.com

Investor Relations (Canada):
Frank Candido
Direct Financial Strategies and Communication Inc.
Tel: 514-969-5530
E-mail: frank.candido@medexusinc.com

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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" and similar 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 with respect to future business operations, the

timing of regulatory applications and approvals and the efficacy and success of certain drug therapies. 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. 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