

# Medexus Granted Authorization by Health Canada to Distribute Treosulfan in Canada

Commences shipments to hospitals under the Special Access Program

Plans underway to apply for full registration in Canada

MONTREAL, March 06, 2019 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "Company" or "Medexus") (TSXV: MDP, OTCQB: PDDPF) today announced that Health Canada has authorized the Company to distribute Treosulfan, a conditioning agent used prior to stem cell transplantation. Authorization was granted via the Special Access Program which allows healthcare practitioners to access non-marketed drugs to treat patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. Medexus plans to file for registration of Treosulfan with Health Canada in 2019 and expects to receive full registration within 12 to 18 months following the application. Medexus acquired the rights to Treosulfan through the acquisition of Medac Pharma, Inc., in the fall of 2018.

Treosulfan is indicated as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation in adult patients with malignant and non-malignant diseases, and in pediatric patients older than one month with malignant diseases (<a href="https://www.ema.europa.eu/en/medicines/human/summaries-opinion/trecondi">https://www.ema.europa.eu/en/medicines/human/summaries-opinion/trecondi</a>). Treosulfan is a significant improvement over current products used as conditioning agents prior to bone marrow transplantation, particularly in children, due to the increased rate of event-free survival after 2 years.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "We are thrilled to have been granted authorization to distribute Treosulfan within Canada, as it demonstrates our commitment to bringing products to market with clear market demand that can help patients live better lives. We have already begun shipments to hospitals across Canada and expect to expand distribution of Treosulfan once the product has received approval as a fully registered product." Mr. d'Entremont continued, "The launch of Treosulfan is further validation of the synergies evident from our recent transformative acquisitions, and illustrates our abilities to leverage the combined product portfolios and North American sales force."

While not an approved product in the US, on December 13, 2018, The European Medicines Agency's Committee for Medical Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of marketing authorization for Treosulfan, intended as a conditioning treatment prior to allogeneic haematopoietic stem cell transplantation. In the US Treosulfan is under clinical development and is being used in clinical trials on patients who desire to try a new treatment approach.

#### **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 include Rasuvo and Metoject, unique formulations 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 more information, please contact:

Ken d'Entremont, Chief Executive Officer Medexus Pharmaceuticals Inc.

Tel.: 905-676-0003

E-mail: <u>ken.dentremont@medexusinc.com</u>

Roland Boivin, Chief Financial Officer Medexus Pharmaceuticals Inc.

Tel.: 514-762-2626 ext. 202

E-mail: <a href="mailto:roland.boivin@medexusinc.com">roland.boivin@medexusinc.com</a>

### **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**

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). 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.



Source: Medexus Pharmaceuticals Inc