June 28, 2021

Medexus Receives Notice of Compliance to Commercialize Treosulfan in Canada

TORONTO and CHICAGO, June 28, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "**Company**" or "**Medexus**") (TSX: MDP) (OTCQX: MEDXF) today announced that it has received a Notice of Compliance ("**NOC**") from Health Canada to commercialize treosulfan, developed by medac GmbH, in Canada, following the satisfactory review of the submission for the bifunctional alkylating agent.

Treosulfan will be marketed in Canada under the brand name Trecondyv® and indicated in combination with fludarabine as part of a conditioning treatment prior to allogeneic hematopoietic stem cell transplantation ("**allo-HSCT**"). To date, Medexus has been distributing treosulfan in Canada only under the Special Access Program pursuant to the authorization received in March of 2019. With this recent decision, Trecondyv® will soon be made available for commercial sale for the treatment adult patients with Acute Myeloid Leukemia ("**AML**") or Myelodysplastic Syndromes ("**MDS**") who are at increased risk for standard conditioning therapies, as well as in pediatric patients older than one year old with AML or MDS.

Ken d'Entremont, CEO, commented, "We are thrilled that Health Canada has approved treosulfan for full scale commercialization under the name Trecondyv®. We believe that there is an unmet need in Canada for this product and are happy to provide patients with this potentially curative treatment solution. We are also pleased that Health Canada has approved this drug for pediatric patients, which we believe is a reflection of the significant survival data that it has demonstrated in clinical trials. This Health Canada decision also gives us further confidence of attaining a positive outcome in the FDA's upcoming decision in connection with our Prescription Drug User Fee Act ("**PDUFA**") date on August 11th, which we hope will allow us to offer the product to patients in the United States."

Kerry Bakewell, Vice President of Specialty Markets for Canadian Operations, noted, "The approval of treosulfan will provide Canadians suffering from AML and MDS with a treatment option that has shown reduced toxicity and improved survival outcomes compared to standard myeloablative regimens. With Gleolan®'s approval last September, this important milestone marks the second Health Canada approval in the last ten months, reinforcing our commitment to bringing life saving medications to the North American markets. We expect to launch Trecondyv® commercially within the third quarter this year and will continue to supply the drug to patients via the Special Access Program until then."

Medexus is in the final stages of extending its licensing partnership with medac GmbH ("medac") to include treosulfan for Canada. Under the terms of the agreement, medac is expected to be responsible for the manufacturing and supply of the drug, while Medexus will be responsible for sales and marketing of the product.

About Medexus

Medexus is a leading innovative and rare disease company 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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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 the timing of a commercial launch in Canada, Company's expectations regarding receipt of FDA approval for treosulfan and the expansion of the Company's partnership with medac. 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 materials filed with the Canadian securities regulatory authorities from time to time, including the Company's most recent annual information form and management's discussion and analysis. 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