September 21, 2021

Medexus Announces Expanded Availability of Trecondyv® (treosulfan) in Canada

TORONTO and CHICAGO, Sept. 21, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "**Company**" or **"Medexus**") (TSX: MDP) (OTCQX: MEDXF) announced today that it has initiated its first commercial shipment of Trecondyv® (treosulfan) in Canada, following the June 28th, 2021 Notice of Compliance by Health Canada, which had previously only been distributed under the Health Canada Special Access Program.

Trecondyv® is a bifunctional alkylating agent developed for use as part of a conditioning treatment for patients undergoing allogeneic hematopoietic stem cell transplantation ("**allo-HSCT**"). Trecondyv® is now available for commercial sale in Canada 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.

Kerry Bakewell, Vice President of Specialty Markets at Medexus, commented, "We are pleased to be able to provide Trecondyv® on a commercial scale to patients who are in need of this treatment. We believe that this product has the potential to become the standard of care in Canada due to its excellent event-free and overall survival data, particularly among at-risk groups. We have had a very positive response among the medical community in Canada thus far and expect sales to ramp up quickly as a result."

Dr. Ivan Pasic, Medical Oncologist, Princess Margaret Cancer Centre, has been using treosulfan under the Special Access Program for several months. Dr. Pasic commented: "In the field of allogeneic hematopoietic cell transplantation, we consistently strive toward reducing transplant-related mortality and one way of achieving this goal is through a reduction in the intensity of the conditioning regimens we use. However, the reduction in conditioning intensity is often accompanied by a corresponding increase in the risk of relapse. Treosulfan represents an exception here in that it provides a way of offering transplantation more safely without a significant increase in relapse risk. In a recent randomized phase III study by Beelen *et al.*, the use of treosulfan-based conditioning in patients with AML or MDS has been associated with a 15% increase in 2-y overall survival and 11% decrease in 2-y transplant-related mortality, without increased risk of relapse, compared to busulfan-based conditioning. Because of this study, we are currently offering treosulfan-based conditioning to all patients with MDS who are ineligible to receive standard myeloablative conditioning because of their age and/or comorbidities. We have been accessing the drug through Health Canada Special Access Program and are looking forward to the announced commercial availability as we are considering potential additional indications at our centre, including its use in patients with AML, in line with the available phase III evidence." In March of 2019, Health Canada granted Medexus authorization to

distribute Trecondyv® 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. On June 28, 2021, the Company received a Notice of Compliance ("**NOC**") from Health Canada to commercialize Trecondyv® and began shipping commercially earlier this month. Medexus continues to assist medac in seeking FDA approval of treosulfan in the US.

September 30th Interest Payment

The Company believes it remains well positioned from a balance sheet perspective, taking into consideration various catalysts and upcoming growth drivers. Nevertheless, the Company believes it is prudent at this time to take advantage of all available options to preserve cash and maintain its healthy balance sheet. Therefore, in accordance with the terms of the convertible debenture indenture entered into between Medexus and Computershare Trust Company of Canada dated as of October 16, 2018 (the "**Indenture**"), the Company has elected to issue common shares in the capital of the Company (the "**Common Shares**"), in lieu of cash, to holders of the Company's 6.0% unsecured convertible debentures (the "**Debentures**") in satisfaction of the $1,246,380 interest payment due to holders of Debentures on September 30, 2021 (the "**Interest Payment**"). Holders of Debentures of record as of September 15, 2021 will receive their pro-rata entitlement of a total of 387,075 Common Shares. The issuance of the Common Shares is subject to the terms of the Indenture as well as receipt of the approval of the Toronto Stock Exchange. Medexus' decision to satisfy the Interest Payment in Common Shares reflects the Company's current focus on protecting the strength of its balance sheet and mitigating the need to raise capital in the near term.

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 hematology, auto-immune disease, 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. The Company has also licensed treosulfan, a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, from medac GmbH for Canada and the United States.

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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 issuance of Common Shares in connection with the upcoming interest payment date for the Debentures and statements regarding the Company's future financing needs and intentions. 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