

August 4, 2021



Medexus Schedules Webinar to Discuss FDA Complete Response Letter for Treosulfan

TORONTO and CHICAGO, Aug. 04, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. ("**Medexus**" or the "**Company**") (TSX: MDP) (OTCQX: MEDXF) today announced that it has scheduled a webinar on Thursday, August 5, 2021 at 10:00 a.m. Eastern Time to discuss the Complete Response Letter (CRL) that the Company's licensor, medac GmbH, recently received from the Food and Drug Administration (FDA) for treosulfan.

As previously disclosed, the New Drug Application (NDA) was submitted in respect of the use of treosulfan in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (allo-HSCT). As expressed in the CRL, the FDA has determined that it cannot approve the NDA in its present form and has provided recommendations specific to additional clinical/statistical data and analyses pertaining to the primary and secondary endpoints of the completed pivotal Phase III study.

Medexus continues to be encouraged by the potential for approval of treosulfan by the FDA in the United States due to the acceptance by other agencies around the world and the excellent survival data that has been demonstrated for at-risk groups. The Company has scheduled the webinar to discuss the implications of the CRL and anticipated pathways to FDA approval. Ken d'Entremont, CEO, and Marcel Konrad, CFO will provide an overview of the CRL, followed by a question-and-answer period.

Medexus CRL Webinar Details

Date: August 5, 2021

Time: 10:00 A.M. Eastern Time

Registration Link: [Medexus CRL Webinar](#)

After registering, you will receive a confirmation email containing information about joining the webinar. Questions may be asked during the webinar or can be emailed in to info@adcap.ca. If you are unable to access Zoom, the webinar will be live streamed and available for replay on YouTube: [Adelaide Capital - YouTube](#).

About Medexus

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 and other cautionary 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 potential for FDA approval of treosulfan in the United States, including next steps in the process for seeking such approval. 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