November 1, 2021

Medexus Pharmaceuticals Announces Type A Meeting with FDA Granted for Treosulfan

TORONTO and CHICAGO, Nov. 01, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. ("**Medexus**" or the "**Company**") (TSX: MDP) (OTCQX: MEDXF) and medac GmbH ("**medac**") today announced that the U.S. Food and Drug Administration ("**FDA**") has granted a Type A meeting to medac for treosulfan, a bifunctional alkylating agent developed for use as part of a conditioning treatment for patients prior to undergoing allogeneic hematopoietic stem cell transplantation. The Type A Meeting has been scheduled to occur on November 23, 2021.

On August 3, 2021, Medexus announced that it had received notice from medac, its licensor for treosulfan, that medac had received a Complete Response Letter ("**CRL**") from the FDA with respect to the New Drug Application for use of treosulfan in the United States. In the CRL, the FDA explained their reasons for non-approval and provided recommendations for how to address the outstanding issues, primarily relating to the provision of additional clinical and statistical data and analyses pertaining to the primary endpoint of the completed pivotal Phase III study. As previously noted, these recommendations were covered by medac's existing development plan for treosulfan, which medac is contractually responsible to execute and fund. The Company believes that the CRL provides a path to review and approval that does not require additional clinical studies, provided it can satisfy the FDA's data and post marketing requirements.

Ken d'Entremont, CEO, commented, "We have been actively working with medac to prepare for its anticipated Type A Meeting and are pleased that it has been granted this meeting in line with our previously anticipated timeline. We remain positive on the outlook for treosulfan in the United States and look forward to continuing discussions with the FDA in order to meet the requirements for approval. We continue to believe that treosulfan has enormous potential in the United States, where the current market leading product, busulfan, reached US$126M in sales prior to genericization. In the meantime, we continue to ramp up sales in Canada, where we commercially launched in September of this year."

Treosulfan was approved by Health Canada in June 2021, under the brand name Trecondyv®, and was granted marketing authorization in combination with fludarabine with the European Commission in June 2019.

About medac GmbH

medac GmbH is a privately held, global pharmaceutical company with a growing pharmaceutical and diagnostics business. Since its foundation in Germany in 1970, medac has been specializing in the treatment of diseases within the indication areas oncology,

hematology, urology and autoimmune disorders. medac is committed to the refinement of existing and the development of new therapeutic products – always with the focus on improving patients' quality of life. medac has become known for developing innovative products also in less common indications. This dedication has resulted in a comprehensive portfolio of pharmaceutical products that help make a difference in the lives of patients. medac continually invests in its product development and manufacturing as well as logistic capacities to meet both patients' needs and the demands of healthcare professionals.

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 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 possibility of a path to review and approval for treosulfan in the United States that does not require additional clinical studies, the outlook and potential for treosulfan in the United States. 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.

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