August 3, 2021

Complete Response Letter Received from FDA for Treosulfan

TORONTO and CHICAGO and WEDEL, Germany, Aug. 03, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. ("**Medexus**" or the "**Company**") (TSX: MDP) (OTCQX: MEDXF) and medac GmbH ("medac") announced today that medac, Medexus' licensor for treosulfan, has received a Complete Response Letter (CRL) from the Food and Drug Administration (FDA) in response to its New Drug Application (NDA) for treosulfan.

As previously disclosed, the NDA was submitted for use of treosulfan in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (allo-HSCT), and both Medexus and medac had been optimistic that a positive decision from the FDA in connection with a planned Prescription Drug User Fee Act ("PDUFA") date on August 11th would allow for a commercial launch of treosulfan in U.S. later this year.

However, 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 and medac are reviewing the letter to determine the appropriate course of action. Medexus and medac will work closely with the FDA to understand and address their comments.

Ken d'Entremont, CEO, commented, "Given the recent Health Canada approval, European Medicines Agency approval in 2019, as well as supporting data from more than 100 publications, we were all surprised by the FDA's response. That being said, Medexus and medac look forward to continuing to work with the FDA to address their requests in a timely manner, and we remain optimistic for a future, albeit delayed, approval of treosulfan in the United States, complete with Orphan Drug Designation. The current standard of care is not suitable for numerous at-risk groups, due to the high toxicity effects, and treosulfan has demonstrated excellent survival data among those groups. We are hopeful that our future communications with the FDA will result in a positive outcome, and we look forward to providing further updates in due course."

Michael Adelman, General Manager of U.S. Operations, commented, "We have been working diligently with medac to prepare for the approval of treosulfan and launch shortly thereafter. We are disappointed with the immediate result, but are encouraged by an incredible amount of support from key opinion leaders and the medical community for use of treosulfan in the United States. With the extensive launch preparations we have taken to date, we are well positioned to meet the expected strong demand for treosulfan. While we work to address all of the FDA's requests, we stand poised to execute our comprehensive launch plan for treosulfan upon approval."

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.

For more information, please contact:

Ken d'Entremont, Chief Executive Officer
Medexus Pharmaceuticals Inc.
Tel.: 905-676-0003
E-mail: ken.dentremont@medexus.com

Marcel Konrad, Chief Financial Officer
Medexus Pharmaceuticals Inc.
Tel.: 312-548-3139
E-mail: marcel.konrad@medexus.com

Investor Relations (U.S.):
Crescendo Communications, LLC
Tel: +1-212-671-1020
Email: mdp@crescendo-ir.com

Investor Relations (Canada):
Tina Byers

Adelaide Capital
Tel: 905-330-3275
E-mail: tina@adcap.ca

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 next steps in the process for seeking FDA approval of treosulfan in the United States and plans for a commercial launch thereafter. 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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