December 2, 2021

Medexus Pharmaceuticals Announces Clear Path to FDA Decision Following medac's Type A Meeting with FDA on Treosulfan

NDA resubmission expected in second calendar quarter 2022 (previously anticipated timeline)
Final FDA decision expected 2 to 6 months after NDA resubmission
No additional Phase III study is required

TORONTO and CHICAGO, Dec. 02, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. ("Medexus" or the "Company") (TSX: MDP) (OTCQX: MEDXF) and medac GmbH ("medac") announced that medac clarified with FDA details with regard to the projected NDA resubmission of treosulfan, an alkylating agent licensed from medac to Medexus, following its Type A Meeting with the U.S. Food and Drug Administration ("FDA").

medac requested and was granted a Type A Meeting with the FDA, held on November 23, 2021, to review medac's resubmission plan for its new drug application ("NDA") for treosulfan and to receive the FDA's guidance. Resubmission is required because the FDA previously issued a Complete Response Letter following their review of medac's original treosulfan NDA.

Medexus and medac have reviewed the meeting minutes and the proposed pathway for resubmission. The requirements for marketing authorization were discussed and the companies are diligently working to fulfill those requirements.

Ken d'Entremont, CEO, stated, "We are pleased with the outcome of medac's productive Type A Meeting with the FDA. We believe this meeting provided medac with the information needed to allow it to resubmit the NDA for treosulfan within our previously anticipated timeframe. Based on the discussions, it is our conclusion that there is a path towards approval that does not involve completing another Phase III study. As a result, we believe that medac will be positioned to resubmit the NDA to the FDA in the second quarter of calendar year 2022. The FDA encouraged medac to maintain open lines of communication and active discussions regarding medac's resubmission activities."

Medexus expects the FDA to make a decision regarding approval of treosulfan within two to six months following the resubmission of the NDA. medac will continue to fund the regulatory costs until approval.

About Treosulfan

Treosulfan is a bifunctional alkylating agent that is used in combination with fludarabine as a

preparative regimen for allogeneic hematopoietic stem cell transplantation. Treosulfan, currently under clinical development in the United States, was recently approved by Health Canada and commercially launched in Canada under the brand name Trecondyv®, and is also commercially available in Europe. Extensive research indicates that treosulfan has the potential to become standard of care in North America.

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.

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.

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):
Victoria Rutherford
Adelaide Capital
Tel: 1-480-625-5772
E-mail: victoria@adcap.ca

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 ability to obtain FDA approval for treosulfan and the possibility of a path to such approval that does not require additional clinical studies, including with respect to Medexus's beliefs regarding the regulatory process with respect to treosulfan, the FDA's views on treosulfan, and the timeline for medac's NDA resubmission and the FDA's decision. 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. Medexus 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 Medexus's materials filed with the Canadian securities regulatory authorities from time to time, including Medexus's most recent annual information form and management's discussion and analysis; future capital requirements and dilution; intellectual property protection and infringement risks; competition (including potential for generic competition); reliance on key management personnel; Medexus's ability to implement its business plan; Medexus's ability to leverage its U.S. and Canadian infrastructure to promote additional growth; regulatory approval by relevant health authorities, including the FDA; product reimbursement by third party payers; patent litigation or patent expiry; litigation risk; stock price volatility; government regulation; and potential third party claims. 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, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

Source: Medexus Pharmaceuticals Inc