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Medexus Pharmaceuticals Announces Resubmission of Treosulfan NDA

Additional data collection and analysis reconfirms confidence in New Drug Application for Treosulfan

NDA resubmission date consistent with previously announced timeline

FDA decision still expected within six months of resubmission

TORONTO and CHICAGO, April 22, 2022 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals (**Medexus**) (TSX: MDP) (OTCQX: MEDXF) and medac, a strategic partner of Medexus, are pleased to announce that medac has resubmitted its New Drug Application for Treosulfan (**NDA**) with the U.S. Food and Drug Administration (**FDA**). The NDA requests approval of Treosulfan in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (**allo-HSCT**). The resubmission includes additional clinical data and statistical analysis relating to the previously-completed phase 3 clinical trial of Treosulfan as well as an update of the integrated summary of safety, which the FDA had requested in their July 2021 Complete Response Letter to medac.

“medac’s comprehensive data collection and analysis reconfirmed our confidence in the results of the phase 3 study, and we are pleased that the FDA will have an opportunity to review this additional information,” commented Ken d’Entremont, Medexus’s Chief Executive Officer. “Within 30 days of resubmission, the FDA will communicate the timeline for their review. We and our partners at medac look forward to an FDA decision within six months from resubmission. An FDA approval would then pave the way for a commercial launch of Treosulfan in the United States within Medexus’s fiscal year 2023.”

Michael Adelman, Medexus’s General Manager, U.S. Operations, commented further: “Treosulfan is orphan drug designated and, if approved, would be the first in a new conditioning treatment class for allo-HSCT Reduced Toxicity Conditioning – providing patients and their physicians with a unique combination of improved survival outcomes compared to reduced-intensity regimens and decreased toxicity compared to standard myeloablative regimens.”

Mr. Adelman continued, “During the extended registration period, we have continued to work diligently with our partners at medac to further prepare for the launch of Treosulfan in the United States. We stand ready to execute our comprehensive launch plan upon approval. We are very hopeful for a favorable FDA decision and believe that, if approved, Treosulfan will become the new standard of care for patients with acute myeloid leukemia and myelodysplastic syndrome undergoing allo-HSCT in North America.”

About Medexus

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform and a portfolio of proven best-in-class products. Our current focus is on the therapeutic areas of hematology, auto-immune diseases, and allergy. We continue to build a highly differentiated company with a growing portfolio of innovative and high-value orphan and rare disease products that will underpin our growth for the next decade.

Our current 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. We also hold exclusive US and Canadian rights to commercialize Gleolan (aminolevulinic acid hydrochloride or ALA HCl), an FDA-approved, orphan drug designated optical imaging agent currently indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

We have also licensed Treosulfan, a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, for commercialization in the United States and Canada. Treosulfan was approved by Health Canada in June 2021 and is marketed in Canada as Trecondyv®. Treosulfan is currently under review by the U.S. Food and Drug Administration.

Our mission is to provide the best healthcare products to healthcare professionals and patients. We strive to deliver on this mission by acting on our core values: Quality, Innovation, Customer Service, and Collaboration.

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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”, “potential”, and similar words or 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 press release include, but are not limited to, statements regarding the timing and expected outcome of the FDA approval process for Treosulfan and a related launch of the product in the United States and expectations regarding the product’s prospects if approved by the FDA. 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; litigation or expiry with respect to patents or other intellectual property rights; 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 are made 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.

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