September 16, 2024

Medexus Provides Update on Treosulfan NDA Review Process and Extended PDUFA Goal Date

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - September 16, 2024) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) has been informed by medac, licensor of Medexus's commercialization rights to treosulfan, that the US Food and Drug Administration has extended the review period for the New Drug Application for treosulfan by three months. The FDA has set a new PDUFA target action date of January 30, 2025.

The FDA notified medac that the Agency requires additional time to review supplemental analyses of previously submitted data that had been provided by medac in response to the FDA's routine information requests, having determined that the additional information constitutes a major amendment, which allows the FDA up to three additional months to complete their review. The FDA has not requested submission of new clinical data.

"We recognize that this development further extends the regulatory review process timeline," commented Ken d'Entremont, Medexus's Chief Executive Officer. "Nevertheless, we are encouraged to see that the FDA remains actively engaged with medac, and we continue to prepare for an approval of treosulfan in the United States and a commercial launch in the first half of calendar year 2025."

The treosulfan NDA seeks approval of treosulfan in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (allo-HSCT) in adult and pediatric patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

About Medexus

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform and a growing portfolio of innovative and rare disease treatment solutions. Medexus's current focus is on the therapeutic areas of oncology, hematology, rheumatology, auto-immune diseases, allergy, and dermatology. For more information about Medexus and its product portfolio, please see the company's corporate website at www.medexus.com and its filings on SEDAR+ atwww.sedarplus.ca.

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Forward-looking statements

Certain statements made in this news release contain forward-looking information within the meaning of applicable securities laws, also known and/or referred to as "forward-looking information" or "forward-looking statements". The words "anticipates", "believes", "expects", "will", "plans", "potential", and similar words, phrases, or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words, phrases, or expressions. Specific forward-looking statements in this news release include, but are not limited to, statements regarding: the potential benefits of treosulfan; the occurrence, timing, and expected outcome of the FDA review process for treosulfan; and, if approved by the FDA, and if the Company's ongoing negotiations with medac to further amend the US treosulfan agreement are successful, the expected timing of any commercial launch of the product in the relevant market and related expectations regarding the product's prospects, and the potential competitive position of the product and anticipated trends and potential challenges in the market in which the product is expected to compete. 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 regulatory guidelines, 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 the assumptions are believed to be reasonable in the circumstances, these risks and uncertainties mean that actual results could differ, and could differ materially, from the expectations contemplated by the forward-looking statements. Material risk factors include, but are not limited to, 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. Without limiting the generality of the foregoing, see "Risk Factors and Risk Management-Possible failure to realize benefits of the US Treosulfan Agreement" in Medexus's most recent MD&A, including in respect of the specified negotiation period currently underway. Accordingly, undue reliance should not be placed on these forward-looking statements, which are made only as of the date of this news release. 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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