June 6, 2024

FDA Accepts for Review Treosulfan NDA Resubmission

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - June 6, 2024) - On Thursday, June 6, 2024, Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) was informed by medac, licensor of Medexus's commercialization rights to treosulfan, that the US Food and Drug Administration has accepted for review medac's April 2024 resubmission of the New Drug Application for treosulfan. Medexus expects that the FDA will complete its review of the treosulfan NDA and issue a decision by October 30, 2024. The treosulfan NDA seeks approval of treosulfan in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients. medac's resubmission provided additional information that had previously been requested by the FDA relating to the pivotal phase 3 clinical trial of treosulfan conducted by medac.

"We are pleased to report this positive new development in the regulatory review process," commented Ken d'Entremont, Medexus's Chief Executive Officer. "We were encouraged to see the FDA engage with medac. We remain optimistic about the prospect of a treosulfan approval in the United States, and about treosulfan's potential in the US market, because we continue to believe that treosulfan would prove to be the gold standard in this therapeutic space, as it has in Europe and Canada. If approved by the FDA, we expect that treosulfan would have a meaningful impact on Medexus's total revenue."

Medexus successfully launched treosulfan in Canada under the brand name Trecondyv® in September 2021, and since launch has gained valuable experience commercializing the product in that market. This success in Canada supports Medexus's optimism regarding treosulfan's potential positive impact in the US market if and when approved.

Under the terms of a September 2023 amendment to Medexus's February 2021 exclusive license agreement relating to commercialization of treosulfan in the United States, Medexus and medac now have a specified negotiation period to agree to a further amendment with respect to any adjustments to the value of unpaid regulatory and sales-based milestone payments that the parties may agree are appropriate in the prevailing circumstances. Medexus will have no obligation to make any milestone payments before the effective date of any such further amendment to the US treosulfan agreement.

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.com.

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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 timing and expected outcome of the FDA review process for treosulfan; and, if approved by the FDA, expectations regarding the product's prospects and competitive position in the market. 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, and, in particular, Medexus's analysis and assessment of the market in which Metoject® competes. 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. 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.

Additional notes

Trecondyv® is approved by Health Canada for sale and use in Canada only and is not intended for export outside Canada. Medexus makes no representation that Trecondyv® is appropriate for, or authorized for sale to or use by, persons who are not located in Canada. For more information about Trecondyv®, including important safety information, see the full product monograph (including patient medication information), which is available on the company's corporate website at www.medexus.com. Trecondyv® is a trademark of medac.

The information in this news release is provided for informational purposes to investors in Medexus securities.

Uniform resource locators, or website addresses, that appear in this news release are intended to be provided as inactive textual references only. Information contained on or accessible through these website addresses is not a part of this news release and is not incorporated by reference into this news release or any of Medexus's public filings.

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