November 18, 2024

Medexus and pan-Canadian Pharmaceutical Alliance (pCPA) Successfully Complete Negotiations for Trecondyv (treosulfan for injection) in Canada

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - November 18, 2024) - Earlier in November 2024, Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) successfully completed a negotiation process with the pan-Canadian Pharmaceutical Alliance seeking to make Trecondyv® (treosulfan for injection) accessible to publicly funded drug programs and patients in Canada. The pCPA is an independent organization whose membership includes the provincial, territorial, and federal governments.

Reaching this important milestone on November 4, 2024 was the result of a collaborative negotiation process with pCPA,[1] and followed publication of final recommendations on reimbursement from Québec's L'Institut National d'Excellence en Santé et en Services Sociaux on March 6, 2024 and from Canada's Drug Agency (formerly CADTH) on March 18, 2024, based on Medexus's July 2023 submissions to those agencies.[2]

"We are very encouraged by this additional vote of confidence in treosulfan," said Richard Labelle, Medexus's Chief Operating Officer. "Approximately three quarters of transplant centers across Canada are already using treosulfan, which is consistent with the strong year-over-year unit demand growth we saw as of September 30, 2024.[3] This latest development emphasizes the need to move quickly through the subsequent steps to public reimbursement of Trecondyv®, and is yet another important indicator of this product's prospects and potential, both in the Canadian market and, if and when approved by the FDA, the US market as well."

The next step in the public reimbursement process will be for participating government organizations to make their respective final decisions on public reimbursement for their regions. Medexus is committed to continuing to work with participating provincial, territorial, and federal government organizations to make Trecondyv® available as soon as possible through public drug plans for the patients who need it.

"Clinicians should always make the best choice possible for their patients, so we are very pleased with this new development, as it will hopefully result in greater physician access to this treatment option across Canada," added Dr Ivan Pasic from Toronto's Princess Margaret Hospital.

[1] pCPA, "Trecondyv (treosulfan)", available at https://www.pcpacanada.ca/negotiation/22608 (accessed November 14, 2024).

[2] INESSS, "Extract notice to the Minister: Trecondyv (alloGCSH)", available at https://www.inesss.qc.ca/en/themes/medicaments/drug-products-undergoing-evaluation-and-evaluated/extract-notice-to-the-minister/trecondyv-6785.html (accessed November 14, 2024), and CDA, "treosulfan", available at https://www.cda-amc.ca/treosulfan (accessed November 14, 2024).

[3] Medexus, news release: "Medexus Announces Strong Fiscal Q2 2025 Results", available at https://www.medexus.com/en_US/investors/financial-results (accessed November 14, 2024) and on SEDAR+. Unit demand for Trecondyv® in Canada remained strong during the 12-month period ended September 30, 2024, which is reflected in the unit demand growth of 49% over the trailing 12-month period ended September 30, 2024.

About Trecondyv® (treosulfan for injection)

Treosulfan is part of a preparative regimen for allogeneic hematopoietic stem cell transplantation, to be used in combination with fludarabine, used in treating eligible patients with acute myeloid leukemia and myelodysplastic syndromes.

Final study results and analysis of the pivotal phase 3 clinical trial of treosulfan conducted by medac GmbH, which was published in the American Journal of Hematology, concluded that the study demonstrates clinically relevant superiority of treosulfan over a widely applied "reduced-intensity conditioning" busulfan regimen with regard to its primary endpoint, event-free survival. The publication also includes favorable conclusions on two key secondary endpoints, finding that overall survival with treosulfan was superior compared to busulfan and that non-relapse mortality for patients in the treosulfan arm was lower than for patients in the busulfan arm. For more information about the study and the publication, including a link to the full publication, see Medexus's June 6, 2022 press release, available via the Investors section of Medexus's corporate website.

During the phase 3 clinical trial of treosulfan, treatment emergent adverse events (TEAEs) were most commonly reported in the system organ classes, or SOCs, of "Gastrointestinal disorders", "General disorders and administration site conditions", and "Musculoskeletal and connective tissue disorders". TEAEs of at least CTCAE Grade III were reported by 54.8% of patients in the treosulfan treatment group. Severe adverse events were reported by 8.5% of patients in the treosulfan treatment group. Overall, TEAEs were reported by 92.6% of patients in the treosulfan treatment group.

For more information about Trecondyv® (treosulfan for injection), including important safety information, see the product monograph, which is available on Health Canada's website at https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=100678.

Treosulfan 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 treosulfan is appropriate for, or authorized for sale to or use by, persons who are not located in Canada. Treosulfan is currently the subject of a regulatory review process with the US Food and Drug Administration. Medexus holds exclusive commercialization rights to treosulfan in Canada and the United States.

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 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", "prospects", 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, information contained in statements regarding any of the following: Medexus's expectations and plans regarding future growth, revenues, and expenses (including in respect of the commercialization of treosulfan and the product-level revenue to be generated from its commercialization in Canada and the United States); the legislative, regulatory, and policy environment in Canada; the potential benefits of treosulfan; the occurrence, timing, and expected outcome of the public reimbursement review process for Trecondyv® and the FDA review process for treosulfan; and, if approved by one or more participating jurisdictions (in the case of public reimbursement process for Trecondyv®) and the FDA (in the case of commercialization of treosulfan in the United States), expectations regarding the product's prospects and performance, its potential adoption and use, 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 and information are based on Medexus's current expectations and assumptions, including factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, and 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. 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® (treosulfan for injection), as discussed in this news release, is a Canadian trademark of medac GmbH. Solely for convenience, trademarks and other protected names and marks referred to in this news release may appear without the "®", "™", or other similar symbols. Each such reference should be read as though it appears with the relevant symbol. Any such references are not intended to indicate, in any way, that the holder or holders will not assert those rights to the fullest extent under applicable law.

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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