December 2, 2024

Medexus and medac Conclude Negotiations to Amend US Treosulfan Agreement, Setting Regulatory Milestone Amounts and Payment Schedule

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - December 2, 2024) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to announce that the company recently entered into a fourth amendment to its February 2021 exclusive license agreement with medac relating to commercialization of treosulfan in the United States.

Among other things, the fourth amendment adjusts the unpaid regulatory milestone payments under the US treosulfan agreement. Upon an FDA approval of treosulfan, Medexus would repay a US$2.5 million credit received from medac in September 2021 and would pay a regulatory milestone amount to medac, based on the language of the product label approved by the FDA, of either US$15 million, or US$20 million if the product label includes non-inferiority but not clinical superiority, or US$45 million if the product label includes clinical superiority. This regulatory milestone amount would be paid in installments as follows:

- one-sixth of the total amount by June 30, 2025,
- one-third of the total amount by October 1, 2025, and
- the remaining amount (50% of the total) by January 1, 2026.

For the lowest regulatory milestone amount, this installment schedule would result in payments of US$2.5 million, US$5 million, and US$7.5 million.

Medexus would be entitled to temporarily defer a portion of the first installment (to the extent, if any, exceeding US$3.25 million) for up to 90 days, the second installment for up to 120 days, and the third installment for up to 30 days, with any deferred amount accruing interest at an interest rate of 9.0% per annum.

"We are pleased to have achieved clarity on the remaining contractual milestones under our agreement and arrived at terms that appropriately reflect the value we see in this product," commented Ken d'Entremont, Chief Executive Officer of Medexus. "We remain optimistic about the prospect of FDA approval no later than January 30, 2025, and we view the lower milestone amounts as the more likely outcome based on the expected labeling of the product. If approved, we continue to believe annual product-level revenue in the United States has the potential to exceed US$100 million within five years after commercial launch, providing a significant uptick to our growth profile."

"Achieving the favorable payment terms of this amendment further strengthens our financial position" added Brendon Buschman, Chief Financial Officer of Medexus. "This structure will allow us to allocate existing capital towards the launch of treosulfan in the United States, and provides us the flexibility to defer 83% of the total regulatory milestone amount to the end of January 2026. This means we can fund these amounts with cash on hand, cash generated from operations, additional debt financing, or the option that best aligns with our strategic objectives at the time of payment."

The fourth amendment also extends the agreed outside date for FDA approval to reflect the current status of the FDA regulatory review process. In addition, in connection with the fourth amendment, Medexus agreed to end a concession previously granted by medac in respect of the supply price for Rasuvo and, in the event Medexus exercises the temporary deferral right discussed above, to a further marginal increase in the per-unit supply price for that product.

Additional information about the terms of the license agreement, including copies of the relevant documents, is included in the company's filings on SEDAR+ at www.sedarplus.ca. The summary in this news release is qualified by reference to the terms of each such document as applicable.

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.

Contacts

Ken d'Entremont | CEO, Medexus Pharmaceuticals
Tel: 905-676-0003 | Email: ken.dentremont@medexus.com

Brendon Buschman | CFO, Medexus Pharmaceuticals
Tel: 416-577-6216 | Email: brendon.buschman@medexus.com

Victoria Rutherford | Adelaide Capital
Tel: 480-625-5772 | Email: victoria@adcap.ca

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 the United States); the potential benefits of treosulfan; the occurrence, timing, and expected outcome of the FDA review process for treosulfan (including the terms of the FDA's approval, if any, and in particular relating to expectations regarding the amount of the regulatory milestone payment that would become payable depending on those terms); Medexus's capital allocation strategy, including expectations regarding availability of cash on hand and funds from operations, cash flow generation, and capital allocation and anticipated cash needs, capital requirements, and needs for and ability to secure additional financing (in particular any milestone payments that may become due under the company's US treosulfan agreement); and, if approved by the FDA, 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.

MEDEXUS PHARMA

To view the source version of this press release, please visit https://www.newsfilecorp.com/release/232026

SOURCE Medexus Pharmaceuticals Inc.