January 22, 2025

Medexus Announces FDA Approval of GRAFAPEX (treosulfan) for Injection and Provides Business Update

Medexus will target a commercial launch in 1H CY2025; potential for annual product-level revenue to exceed US$100 million within five years after commercial launch

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - January 22, 2025) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to provide a business update regarding the successful completion of the regulatory review process for GRAFAPEX™ (treosulfan) for injection with the US Food and Drug Administration and, in addition, to announce preliminary estimates of the company's operating and financial results for the company's third fiscal quarter ended December 31, 2024 (which remain subject to completion of Medexus's financial closing procedures). All dollar amounts in this news release are in US dollars unless specified otherwise.

FDA approval of GRAFAPEX™ (treosulfan) for injection

On January 22, 2025, Medexus was informed that the FDA approved GRAFAPEX™, an alkylating agent, with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients one year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). GRAFAPEX™ holds Orphan Drug Designation under the Orphan Drug Act, meaning that the product will benefit from up to seven-and-a-half years of regulatory exclusivity in the FDA-approved indication. Medexus holds exclusive commercial rights to GRAFAPEX™ in the United States under a February 2021 exclusive license agreement with medac GmbH.

"We are pleased to report this positive development, which marks a strategically important step forward for our business and, importantly, will now benefit eligible patients across the United States," commented Ken d'Entremont, Medexus's Chief Executive Officer. "Not only will GRAFAPEX™ make a substantial contribution to alloHSCT in the United States, but it also solidifies Medexus's leadership position in this therapeutic field."

"We are targeting a commercial launch in the first half of calendar year 2025, and given our recent experience in Canada we are very optimistic about the potential of GRAFAPEX™ in the US market," added Richard Labelle, Medexus's Chief Operating Officer. "We anticipate that GRAFAPEX™ will have a meaningful impact on Medexus's total revenue and believe that annual product-level revenue in the United States has the potential to exceed US$100 million within five years after commercial launch."

"This FDA approval provides a useful option for adult and pediatric patients, with the potential to enhance overall survival while minimizing side effects," said Dr Filippo Milano, a stem cell transplant physician-scientist and principal investigator in clinical trials using

treosulfan as part of a conditioning regimen.

As previously announced, the regulatory milestone amount payable to medac under the fourth amendment to the February 2021 exclusive license agreement between the parties is based on the language of the product label approved by the FDA. Based on the terms of the approval, including the FDA-approved product label, Medexus has determined that medac will earn a $15 million regulatory milestone amount. The final amount is subject to review and confirmation by the parties in light of the terms of the agreement. The regulatory milestone amount will be payable in installments, subject to Medexus's right to temporarily defer installment amounts, on terms described in Medexus's December 2, 2024 press release, available via the Investors section of Medexus's corporate website. For a $15 million regulatory milestone amount, this installment schedule will result in payments of US$2.5 million by June 30, 2025, US$5 million by October 1, 2025, and US$7.5 million by January 1, 2026 – subject to Medexus's temporary deferral option in respect of the second and/or third such payments. Also as previously announced, given the FDA approval of GRAFAPEX™, Medexus will now promptly repay a US$2.5 million credit received from medac in September 2021.

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.

Preliminary estimates for fiscal Q3 2025

Medexus remains focused on delivering strong revenue growth and overall performance across the company's entire portfolio of products in both the United States and Canada. This important new development for Medexus regarding GRAFAPEX™ arrives on the heels of what is expected to be a solid fiscal Q3 2025, and includes an estimated $1.9 million in fiscal Q3 2025 investments in personnel and infrastructure that were made to prepare for this recent positive FDA decision.

Medexus currently expects key selected highlights for fiscal Q3 2025 to include the following -

- Revenue between $29.5 million and $30.5 million for the three-month period ended December 31, 2024, representing a year-over-year increase of at least 17% over $25.2 million for fiscal Q3 2024, attributable in part to continuing growth in net sales of Rupall, and an approximately $2.0 million beneficial impact of customer buying patterns and related timing of orders of IXINITY relative to patient unit demand in fiscal Q3 2025.

- Adjusted EBITDA between $5.5 million and $6.0 million for the three-month period ended December 31, 2024, representing a year-over-year increase of at least 70% over $3.2 million for fiscal Q3 2024, primarily attributable to the effects of the company's ongoing financial discipline efforts, together with the effect of customer buying patterns mentioned above, and partially offset by the estimated $1.9 million of GRAFAPEX™ personnel and infrastructure investments mentioned above. (Refer to "Non-GAAP measures" at the end of this press release for information about Adjusted EBITDA.)

- Available liquidity of approximately $8.5 million (December 31, 2024), consisting of cash and cash equivalents, compared to $5.3 million (March 31, 2024).

- Operating income between $3.5 million and $4.0 million for the three-month period ended December 31, 2024, representing a year-over-year increase of at least 123% over $1.6 million for fiscal Q3 2024.

- Net income between $(0.5) million and $2.0 million for the three-month period ended December 31, 2024, compared to $(0.5) million for fiscal Q3 2024. Final reported net income for fiscal Q3 2025 will depend on completion of Medexus's financial closing procedures, including in respect of current and deferred income tax expense amounts.

The expected results discussed in this news release are preliminary estimates only, as Medexus's financial closing procedures remain subject to completion, and have not been reviewed or audited by the company's auditors. All such figures are based on information currently available to Medexus management and are subject to change and adjustment as Medexus's financial results for fiscal Q3 2025 are finalized. Accordingly, final reported results may differ, and may differ materially, from these preliminary estimates, and investors therefore should not place undue reliance on any such preliminary estimates. All such preliminary estimates constitute forward-looking information within the meaning of applicable securities laws, are based on a number of assumptions, and are subject to a number of risks and uncertainties. For more information, see "Forward-looking statements" below. Medexus currently expects to file its financial statements and MD&A for fiscal Q3 2025 after markets close on February 5, 2025.

Medexus expects key operational highlights for fiscal Q3 2025 to include the following –

- IXINITY® (US): Continuing slight decline in unit demand, reflecting the continued effect of previously disclosed trends and factors.

- Rupall® (Canada): Continuing strong unit demand growth, reflecting successful execution of the company's initiatives in advance of the expiration of Rupall's market exclusivity in late January 2025.

- Rasuvo® (US) and Metoject® (Canada): Continuing strong unit demand in the face of sustained competition and the continued effect of previously disclosed trends and factors.

- Gleolan® (US): Continuing slightly positive trend in US unit demand growth, reflecting the response to the company's commercialization efforts and successful execution of the company's commercial plan to date. There nevertheless continue to be disagreements with the licensor regarding the terms of the US Gleolan agreement, which Medexus continues to seek to resolve through mutual negotiation and pursuant to the terms of the US Gleolan agreement, including its dispute resolution process. Medexus is confident that it has performed its obligations under the US Gleolan agreement and, pending resolution of the US Gleolan agreement, whether by mutually acceptable agreement or otherwise in accordance with its existing terms, currently intends to continue commercializing Gleolan in the United States through to at least March 31, 2025 in accordance with and subject to the terms of the US Gleolan agreement. (See also "Risk Factors and Risk Management-Commercial contract

disputes" in Medexus's most recent MD&A.)

- Trecondyv® (treosulfan) (Canada): Continuing strong unit demand growth, reflecting successful execution of the company's initiatives in support of the product, but which does not yet include the effect of the successful completion of the negotiation process with the pan-Canadian Pharmaceutical Alliance and any subsequent decisions by participating government organizations on public reimbursement of Trecondyv for their regions and jurisdictions.

About GRAFAPEX™ (treosulfan) for injection

GRAFAPEX™ (treosulfan) for injection, an alkylating agent, is indicated in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients one year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). GRAFAPEX™ holds Orphan Drug Designation under the Orphan Drug Act, meaning that the product will benefit from a seven-year period of regulatory exclusivity in the FDA-approved indication.

Full prescribing information for GRAFAPEX™ will be available on the Drugs@FDA drug database at www.fda.gov.

Efficacy was evaluated in MC-FludT.14/L Trial II (NCT00822393), a randomized active-controlled trial comparing treosulfan to busulfan with fludarabine as a preparative regimen for allogeneic transplantation. Eligible patients included adults 18 to 70 years old with AML or MDS, Karnofsky performance status ≥60%, and age ≥50 years or hematopoietic cell transplantation comorbidity index [HCTCI] score >2. There were 570 patients randomized to treosulfan (n=280) or busulfan (n=290).

The major efficacy outcome measure was overall survival (OS), defined as the time from randomization until death from any cause. The hazard ratio for OS (stratified by donor type and risk group) compared to busulfan was 0.67 (95% CI: 0.51, 0.90) in the randomized population, 0.73 (95% CI: 0.51, 1.06) in patients with AML, and 0.64 (95% CI: 0.40, 1.02) in patients with MDS.

The most common adverse reactions (≥20%) were musculoskeletal pain, stomatitis, pyrexia, nausea, edema, infection, and vomiting. Selected Grade 3 or 4 nonhematological laboratory abnormalities were increased GGT (gamma-glutamyl transferase), increased bilirubin, increased ALT (alanine aminotransferase), increased AST (aspartate aminotransferase), and increased creatinine.

The recommended treosulfan dose is 10 g/m2 daily on days -4, -3, and -2 in combination with fludarabine 30 mg/m2 daily on days -6, -5, -4, -3, and -2, and allogeneic hematopoietic stem cell infusion on day 0.

For more information about GRAFAPEX™, including important safety information, see the full prescribing information, which will be available on the Drugs@FDA drug database at www.fda.gov. For more information about the pivotal phase 3 clinical trial of treosulfan conducted by medac GmbH, including its methods, results, and conclusions, and about the publication of the study in the American Journal of Hematology, including a link to the full publication, see Medexus's June 6, 2022 press release, including the section entitled "About

the study", available on the Investors-News & Events section of Medexus's corporate website.

GRAFAPEX™ (treosulfan) for injection is approved by the FDA for sale and use in the United States only and is not intended for export outside the United States. Medexus makes no representation that GRAFAPEX™ (treosulfan) for injection is appropriate for, or authorized for sale to or use by, persons who are not located in 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 GRAFAPEX™ (treosulfan) for injection and the product-level revenue to be generated from its commercialization in the United States); the potential benefits of GRAFAPEX™ (treosulfan) for injection; the expected timing of any commercial launch of the product in the United States and related expectations regarding GRAFAPEX™ (treosulfan) for injection and the product's prospects and performance, including in respect of its potential adoption and use in the United States and any related product-level revenue, and including the potential competitive position of the product and anticipated trends and potential challenges in the market in which the product is expected to compete; the expected outcome of Medexus's and medac's ongoing evaluation of the milestone amount payable under the US treosulfan agreement; 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 expectations regarding payment of the regulatory milestone payment that became payable under the company's GRAFAPEX agreement upon the occurrence of, and which depends on the terms of, the FDA's approval); and the preliminary estimates of, and any commentary regarding, Medexus's operating and financial results for the company's fiscal Q3 2025 (which remain subject to completion of Medexus's financial closing and other procedures). Finally, forward-looking statements in this news release include statements regarding the occurrence, timing, and expected outcome, and any related consequences for the product and Medexus, of Medexus's ongoing negotiations and disagreements with the licensor of Medexus's commercialization rights to Gleolan with respect to the US Gleolan agreement, including any informal and/or formal dispute resolution processes that the parties are currently pursuing and will continue to pursue in future, and otherwise regarding the business relationship of the parties in the United States and Canada. 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. In particular, and without limiting the generality of the foregoing, Medexus's estimate of product-level revenue from commercialization of GRAFAPEX™ (treosulfan) for injection in the United States is based on a number of such factors and assumptions, as described in Medexus's most recent annual information form and management's discussion and analysis, and including Medexus's planned commercial, market access, and medical strategies, the success of which will depend in part on the US regulatory landscape and related dynamics, including potential future changes to each, and can introduce and affect exposure to commercial, legal, and regulatory risk. 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. In addition, specific risks and uncertainties relevant to the content of this news release include, among other things: the uncertainties inherent in research initiatives (including the possibility of unfavorable new data and further analyses of existing data); the risk that data are subject to differing interpretations and assessments by relevant third parties; and whether relevant third parties will be satisfied with the design and methodology of and results from the relevant study, which will depend on many factors, including determinations as to whether the product's benefits outweigh its known risks and determinations of the product's efficacy and cost-effectiveness in the context of a given facility (which varies by facility type). 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

Solely for convenience, trademarks and other protected names and marks referred to in this news release sometimes 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.

Non-GAAP measures

Company management uses, and this news release refers to, financial measures that are not recognized under IFRS and do not have a standard meaning prescribed by generally accepted accounting principles (GAAP) in accordance with IFRS or other financial or accounting authorities (non-GAAP measures). These non-GAAP measures may include "non-GAAP financial measures" and "non-GAAP ratios" (each defined in National Instrument 52-112, Non-GAAP and Other Financial Measures Disclosure). Medexus's method for calculating these measures may differ from methods used by other companies and therefore these measures are unlikely to be comparable to similarly-designated measures used or presented by other companies.

In particular, management uses Adjusted EBITDA as a measure of Medexus's performance. EBITDA (earnings before interest, taxes, depreciation, and amortization) and Adjusted EBITDA are non-GAAP financial measures.

An explanation and discussion of each of these non-GAAP measures, including their limitations, is set out under the heading "Preliminary Notes-Non-GAAP measures" in Medexus's most recent management's discussion and analysis, and are hereby incorporated by reference. A reconciliation of Adjusted EBITDA to the most directly comparable IFRS measure can be found under the heading "Reconciliation of Adjusted EBITDA to Net Income (Loss)" below.

Reconciliation of Adjusted EBITDA to Net Income (Loss)

The following table is derived from and should be read together with Medexus's interim condensed consolidated statement of operations for the three- and nine-month periods ended December 31, 2023. This supplementary disclosure is intended to more fully explain disclosures related to Adjusted EBITDA and provides additional information related to Medexus's operating performance. However, Medexus's non-GAAP measures have limitations as analytical tools and should not be considered in isolation or as a substitute for analysis of Medexus's financial information as reported under IFRS.

(Amounts in $ '000s)	**Three-month periods ended December 31**	
	2023	**2022**
Net loss	(534)	(1,507)
Add back:		

Depreciation and amortization (property, equipment, intangible assets)	1,448	1,515
Interest expense	2,656	3,552
Income tax expense (recovery)	(261)	547
EBITDA	3,309	4,107
Add back:		
Share-based compensation	211	436
Transaction-related fees	–	–
Termination benefits	–	372
Foreign exchange loss (gain)	(293)	(338)
Unrealized gain (loss) on fair value of derivatives	–	646
Adjusted EBITDA	**3,227**	**5,223**

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