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Medexus Provides Update on Progress of Commercialization of GRAFAPEX (treosulfan) for Injection

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - April 7, 2025) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to provide a business update on the progress of the commercial launch of GRAFAPEX™ (treosulfan) for Injection in the United States and announce company management's participation in two upcoming investor conferences.

Medexus has seen an encouraging market response to GRAFAPEX™ in the weeks since the February 24 commercial launch of the product. Several procedures using commercially available GRAFAPEX™ have already occurred, which is consistent with company expectations regarding initial institutional uptake and patient-level demand for the product. Initial formulary inclusion determinations, both by national payors and individual healthcare institutions, are another promising indicator of the product's commercial potential, with progress to date likewise consistent with company expectations. And, on February 28, National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of leading cancer centers devoted to patient care, research, and education, included treosulfan in its NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).^

"We have made good progress already, in the handful of weeks since commercial launch," said Ken d'Entremont, Medexus's Chief Executive Officer. "The rate of formulary inclusion will be a key driver of GRAFAPEX™ performance over the coming quarters. We have sold product to 16 unique institutions, and we expect that we will achieve broad formulary coverage for GRAFAPEX™ as we continue our commercialization efforts. This positive initial response supports our expectation that GRAFAPEX™ will be accretive to quarterly operating cash flows by fiscal Q4 2026."

"We anticipate the annual product-level Adjusted Gross Margin* of GRAFAPEX™ to be approximately 80%," added Brendon Buschman, Medexus's Chief Financial Officer. "This would compare favorably to the portfolio-wide Adjusted Gross Margin* we have achieved in recent fiscal quarters, being 56.3% for fiscal Q3 2025 and 59.5% for fiscal Q2 2025. Combined with our expectation of at least US$100 million in annual product-level revenue within five years after commercial launch, which this initial uptake makes us now more confident in than ever, we continue to see GRAFAPEX™ as being accretive to the portfolio and the company in the coming years."

As another indicator of the tailwinds supporting the GRAFAPEX™ launch in the United States, members of the medical and scientific community presented 34 presentations and abstracts relating to treosulfan at the 2025 Annual Meeting of the EBMT (formerly known as the European Society for Blood and Marrow Transplantation), a congress for all those

involved in the care of transplant and cellular therapy patients, in Florence (Italy) from March 30 to April 2, 2025.

"We are extremely pleased with this early progress," concluded Virginie Bernier PhD, Vice President—Hemato-Oncology at Medexus. "Performance to date, and the response from the market and the attention to treosulfan from the medical and scientific community, supports our confidence that GRAFAPEX™ will make a substantial contribution to alloHSCT in the United States, and also solidify Medexus's leadership position in this therapeutic field."

Medexus is aware that the United States has recently implemented new and/or increased tariffs on imports into the United States and additional such tariffs or restrictions may be forthcoming. Medexus is monitoring this evolving international trade situation and will evaluate the potential impact of these developments on its revenue and cost structure in due course.

Company management will be available to discuss the company's commercialization activities at the LD Micro Invitational XV in New York from April 9 to 10, 2025 and the 2025 Bloom Burton & Co. Health Care Investor Conference in Toronto from May 5 to 6, 2025. Details regarding Medexus's participation will be available on the Investors—News & Events section of Medexus's corporate website.

^ *In accordance with NCCN guidance on "Referencing the NCCN Guidelines in Corporate Press Releases" (available at www.nccn.org/docs/default-source/business-policy/referencing-nccn-content-in-press-release.pdf?sfvrsn=44503ce3_1) (accessed April 4, 2025), Medexus includes here the following statement on "materials containing NCCN Content": "NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way."*

** Refer to "Non-GAAP measures" at the end of this news release for information about Adjusted Gross Margin.*

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™ is 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 (including boxed warning), see the full prescribing information, which is 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 news 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.

Medexus Pharma, Inc. holds exclusive commercial rights to GRAFAPEX™ in the United States under a February 2021 exclusive license agreement with medac GmbH.

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 hematology-oncology and allergy, dermatology, and rheumatology. 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+ at www.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", "budget", "potential", "targets", "could", "estimates", "expects", "forecasts", "goals", "intends", "may", "might", "objective", "outlook", "plans", "projects", "schedule", "should", "will", "would", "prospects", and "vision", or 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 in respect of the commercialization of GRAFAPEX™ (treosulfan) for Injection and the product-level revenue to be generated from and operating expenses associated with its commercialization in the United States, together with related measures such as gross margin and Adjusted Gross Margin (including Adjusted Gross Profit (Loss)) (discussed below in this news release), and specifically including the occurrence, timing, and rate of changes in those indicators; expectations that GRAFAPEX™ (treosulfan) for Injection will be accretive to quarterly operating cash flows by fiscal Q4 2026; the potential benefits of GRAFAPEX™ (treosulfan) for Injection; expectations regarding the evolving international trade situation (including the occurrence, timing, magnitude, and potential applicability of tariffs or restrictions on or otherwise affecting the company's products or components of those products) and any related evaluation of the potential impact of these developments on the company's revenue and cost structure (including on measures such as gross margin and Adjusted Gross Margin (including Adjusted Gross Profit (Loss))); expectations regarding the commercialization of GRAFAPEX™ (treosulfan) for Injection and the product's prospects and performance, including in respect of its potential adoption and use in the United States, its level of contribution to alloHSCT in the United States, and its, and the company's, potential competitive position; and anticipated trends and potential challenges in the market in which the product is expected to compete. The forward-looking statements and information included in this news release 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 most recently described in Medexus's most recent management's discussion and analysis, including the wholesale acquisition cost for GRAFAPEX™ (treosulfan) for Injection (which will likely change from time to time over the life cycle of the product), 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). Further such risks and uncertainties include, among other things, risks and uncertainties associated with the legislative, regulatory, and policy environment in the United States, and other markets or jurisdictions, and, in general, the evolving international trade situation in respect of tariffs or restrictions on or otherwise affecting pharmaceutical or biologic products, including the company's products or components of those products. 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 can 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", "supplementary 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 gross margin and Adjusted Gross Margin (including

Adjusted Gross Profit (Loss)) as a measure of Medexus's performance. Adjusted Gross Profit (Loss) (gross profit (loss) before amortization of intangible assets) is a non-GAAP financial measure, gross margin (gross profit (loss) divided by total revenue, expressed as a percentage) is a supplementary financial measure and Adjusted Gross Margin (Adjusted Gross Profit divided by total revenue, expressed as a percentage) is a non-GAAP ratio.

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 the Adjusted Gross Margin figures referenced in this news release, including the corresponding Adjusted Gross Profit and gross margin figures, to the most directly comparable IFRS measure can be found under the headings "Preliminary Notes—Non-GAAP measures—Adjusted Gross Profit (Loss) and Adjusted Gross Margin" in Medexus's MD&A for fiscal Q3 2025 and fiscal Q2 2025, and are hereby incorporated by reference.



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