August 5, 2025

# GRAFAPEX (treosulfan) for Injection Receives CMS Approval of New Technology Add-On Payment (NTAP) for Eligible Cases in CMS's Fiscal Year 2026

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - August 5, 2025) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to announce that the US Centers for Medicare & Medicaid Services (CMS) has approved New Technology Add-On Payment (NTAP) reimbursement for eligible cases involving the use of GRAFAPEX™ (treosulfan) for Injection for CMS's fiscal year 2026, which runs from October 1, 2025 to September 30, 2026.*

The NTAP program is designed to provide temporary supplemental reimbursement to institutions that use designated new higher-cost medical technologies in the first few years after introduction to the market. To receive NTAP approval, designated technologies must demonstrate substantial clinical improvement in the diagnosis or treatment of Medicare beneficiaries compared to existing alternatives.^

Starting October 1, 2025, eligible procedures involving the use of GRAFAPEX™ will be eligible for additional reimbursement through the NTAP program. Cases involving the use of GRAFAPEX™ that are eligible for NTAP will be identified by ICD-10-PCS codes XW03388 or XW04388 and will benefit from a maximum NTAP of $21,411 for CMS's fiscal year 2026. The GRAFAPEX™ approval was one of only five for CMS's fiscal year 2026 under the new technology add-on payment traditional pathway, out of the 13 applications considered by CMS.

"This development is an important reimbursement milestone for GRAFAPEX™," said Virginie Bernier PhD, Vice President-Hemato-Oncology at Medexus. "We appreciate CMS's support of GRAFAPEX™, first through its approval of transitional pass-through status under Medicare's hospital outpatient prospective payment system (OPPS) and assignment of a permanent HCPCS Level II coding system "J code" for reporting and billing, and now with inclusion in the NTAP program. Together, these actions will help ensure Medicare beneficiaries can more consistently receive GRAFAPEX™ in both inpatient and outpatient settings."

Medexus continues to see a positive response to GRAFAPEX since the US commercial launch of the product in February 2025. As of June 30, 2025, nine large commercial payers, together covering an estimated 48 million patient lives, and 14 individual healthcare institutions, representing 8% of the 180 transplant centers in the United States, have made positive formulary inclusion determinations, a promising indicator of the product's commercial potential, with progress to date consistent with Company expectations. An

additional 29 commercial payers have added GRAFAPEX on their "prior authorization" lists. Wholesaler data as of June 30, 2025 shows that 37 of the 180 transplant centers have already ordered GRAFAPEX for procedures in their institutions, which is likewise consistent with company expectations regarding initial institutional uptake and patient-level demand for the product.

** CMS, "FY 2026 IPPS Final Rule Home Page", available at www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page (accessed August 1, 2025).*

*^ CMS, "New Medical Services and New Technologies", available at www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies (accessed August 1, 2025).*

**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.

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 agreement with medac GmbH. For more information about the terms of the GRAFAPEX agreement, see Medexus's most recent annual information form. A copy of the GRAFAPEX agreement, including all amendments, is included in the company's filings on SEDAR+ at www.sedarplus.ca.

**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 and 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+ 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", "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 net revenue to be generated from and operating expenses associated with its commercialization in the United States; the potential benefits of GRAFAPEX™ (treosulfan) for Injection; expectations regarding the commercialization of GRAFAPEX™ (treosulfan) for Injection and the product's prospects and performance (and the identification

and importance of indicators thereof), including in respect of its potential adoption and use in the United States (and, in particular, its availability to Medicare patients, and the level of consistency thereof, as a result of NTAP approval, transitional pass-through status under OPPS, and assignment of a permanent "J code", as described in this news release), 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. 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 risk that information and data are subject to differing interpretations and assessments by relevant third parties (including the possibility of unfavorable new information or data and further analyses of existing information or data) and whether relevant third parties will be satisfied with the relevant information and data, 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. 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.


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