February 24, 2025

Medexus Announces Commercial Availability of GRAFAPEX (treosulfan) for Injection

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - February 24, 2025) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to announce that GRAFAPEX™ (treosulfan) for Injection is now commercially available in the United States.

"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 have achieved a commercial launch even earlier in calendar year 2025 than previously anticipated, around one month after FDA approval, with orders already received now that product is commercially available," added Richard Labelle, Medexus's Chief Operating Officer. "Given our recent experience in Canada we are very optimistic about the potential of GRAFAPEX™ in the US market. 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."

"We were encouraged by the level of positive feedback we heard at the 2025 Tandem Meetings (Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR) earlier this month," concluded Virginie Bernier PhD, Vice President—Hemato-Oncology at Medexus. "We are already aware of requests for GRAFAPEX™ in connection with urgent patient needs, and we have begun engaging with several key US institutions interested in learning about GRAFAPEX™, so we are glad that this product is now FDA approved and available to benefit eligible patients."

Medexus has established a wholesale acquisition cost for GRAFAPEX™ in the United States of US$3,050 per 5-gram vial and US$610 per 1-gram vial. The dosage form for GRAFAPEX™ is treosulfan as a lyophilized powder in a single-dose vial for injection.

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, 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 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.

Medexus 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.

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", "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 (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; and expectations regarding the commercial launch 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 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 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). 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.

MEDEXUS PHARMA

To view the source version of this press release, please visit https://www.newsfilecorp.com/release/241949

SOURCE Medexus Pharmaceuticals Inc.