

Medexus and Ontario's Provincial Health Services Successfully Complete Agreements for Public Reimbursement of Trecondyv (treosulfan for injection) in Ontario, Canada

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - February 4, 2025) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) recently completed listing agreements with Ontario's Ministry of Health (Ontario Public Drug Programs) and Ontario Health (Cancer Care Ontario) for Trecondyv® (treosulfan for injection). The Ontario Public Drug Programs will now reimburse eligible claims made for Trecondyv®, subject to satisfaction of any relevant conditions set out in the agreements.¹

"This important development is another reimbursement milestone following the successful completion of the pCPA negotiation process for Trecondyv®," said Richard Labelle, Medexus's Chief Operating Officer. "It further demonstrates our commitment to seeking and quickly achieving public reimbursement of Trecondyv® across Canada, and is yet another important indicator of the prospects and potential of our treosulfan products - both Trecondyv® in the Canadian market and, in the US market, GRAFAPEX™ (treosulfan) for Injection, which was recently approved by the FDA."²

The next step in the Trecondyv® public reimbursement process will be for other remaining government organizations to make their respective final decisions on public reimbursement for their regions or jurisdictions. Medexus is committed to continuing to work with these other participating provincial, territorial, and federal government organizations to make Trecondyv® available as soon as possible through public drug plans for the patients who need it.

¹ Cancer Care Ontario, "Drug Formulary", available at www.cancercareontario.ca/en/search_2?field_type_of_contents=1&home_search=trecondyv (accessed February 3, 2025).

² Medexus, news release: "Medexus Announces FDA Approval of GRAFAPEX (treosulfan) for Injection and Provides Business Update", available at https://www.medexus.com/en_US/news-media/press-releases/detail/176/medexus-announces-fda-approval-of-grafapex-treosulfan-for (accessed January 30, 2025) and on SEDAR+. See "About GRAFAPEX™ (treosulfan) for Injection" below.

About Trecondyv® (treosulfan for injection)

Treosulfan is part of a preparative regimen for allogeneic hematopoietic stem cell

transplantation, to be used in combination with fludarabine, used in treating eligible patients with acute myeloid leukemia and myelodysplastic syndromes.

Final study results and analysis of the pivotal phase 3 clinical trial of treosulfan conducted by medac GmbH, which was published in the American Journal of Hematology, concluded that the study demonstrates clinically relevant superiority of treosulfan over a widely applied "reduced-intensity conditioning" busulfan regimen with regard to its primary endpoint, event-free survival. The publication also includes favorable conclusions on two key secondary endpoints, finding that overall survival with treosulfan was superior compared to busulfan and that non-relapse mortality for patients in the treosulfan arm was lower than for patients in the busulfan arm. For more information about the study and the publication, including a link to the full publication, see Medexus's June 6, 2022 press release, available via the Investors section of Medexus's corporate website.

During the phase 3 clinical trial of treosulfan, treatment emergent adverse events (TEAEs) were most commonly reported in the system organ classes, or SOCs, of "Gastrointestinal disorders", "General disorders and administration site conditions", and "Musculoskeletal and connective tissue disorders". TEAEs of at least CTCAE Grade III were reported by 54.8% of patients in the treosulfan treatment group. Severe adverse events were reported by 8.5% of patients in the treosulfan treatment group. Overall, TEAEs were reported by 92.6% of patients in the treosulfan treatment group.

Trecondyv® (treosulfan for injection) is approved by Health Canada for sale and use in Canada only and is not intended for export outside Canada. Medexus makes no representation that Trecondyv® is appropriate for, or authorized for sale to or use by, persons who are not located in Canada. For more information about Trecondyv® (treosulfan for injection), including important safety information, see the product monograph, which is available on Health Canada's website at https://health-products.canada.ca/dpd-bdpp/info? lang=eng&code=100678.

About GRAFAPEX™ (treosulfan) for Injection

On January 22, 2025, Medexus was informed that the FDA approved GRAFAPEX™ (treosulfan) for Injection, 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™ 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™ is appropriate for, or authorized for sale to or use by, persons who are not located in the United States. For more information about GRAFAPEX™, including indications and important safety information (including boxed warning), see the full prescribing information for GRAFAPEX™ (treosulfan) for Injection, which is available on the product's website at www.grafapex.com and is or will be available on the Drugs@FDA drug database at www.grafapex.com and is or will be available on the Drugs@FDA drug

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+ 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: <u>brendon.buschman@medexus.com</u>

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 Trecondyv® (treosulfan for injection), in Canada, and GRAFAPEX™, in the United States, and the product-level revenue to be generated from their commercialization); the legislative, regulatory, and policy environment in Canada; the potential benefits of Trecondyv® and GRAFAPEX™; the occurrence, timing, and expected outcome of the public reimbursement review process for Trecondyv® by one or more remaining participating jurisdictions; and 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, including if approved by one or more participating jurisdictions, in the case of public reimbursement process for Trecondyv®. 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 forwardlooking 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 forwardlooking 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 forwardlooking statements to reflect new information, subsequent or otherwise.

Additional notes

Medexus holds exclusive commercialization rights to Trecondyv® in Canada and to GRAFAPEX™ in the United States.

Trecondyv® (treosulfan for injection), as discussed in this news release, is a Canadian trademark of medac GmbH. Solely for convenience, trademarks and other protected names and marks referred to in this news release may 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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