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# Medexus Announces License and Supply Deal for UM171 Cell Therapy in Canada

**UM171 Cell Therapy is conditionally approved in Europe as Zemcelpro® (dorocubichel)**

**Securing Canadian rights to a proprietary advanced clinical-stage product candidate developed in Canada adds to Medexus's medium-term product pipeline and helps build a North American allo-HSCT franchise**

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - June 9, 2026) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to announce that the company has secured exclusive Canadian rights to commercialize UM171 Cell Therapy, a proprietary advanced clinical stage investigational drug product that recently received conditional marketing authorization in Europe from the European Commission (or EC) as Zemcelpro® (dorocubichel), in a license and supply deal with ExCellThera, a blood stem cell expansion and metabolic fitness company, and Cordex Biologics, its wholly owned subsidiary. Zemcelpro® is a novel personalized cryopreserved hematopoietic stem cell transplantation product containing two components, namely UM171-expanded CD34+ cells (dorocubichel) and unexpanded CD34- cells, each derived from the same cord blood unit. The UM171 molecule and technology behind Zemcelpro® was discovered and developed in Canada by scientists at the Universite de Montreal. The product is used to treat hematological malignancies (blood cancers), such as leukemias and myelodysplasias. Given its current stage of development in Canada, Medexus does not expect to begin commercializing the product before calendar year 2028 or, depending on available regulatory pathways, possibly calendar year 2031.

"This product candidate is an excellent strategic fit with treosulfan, our existing hemato-oncology product, which we commercialize in Canada as Trecondyv® (treosulfan for injection)," said Ken d'Entremont, Chief Executive Officer of Medexus. "Our organization is already well acquainted with the allo-HSCT field, and, although the field continues to rapidly evolve, we see this product candidate as an important potential contribution to the Canadian market and to our medium-term product pipeline."

There were more than 843 allogeneic hematopoietic stem cell transplantation (or allo-HSCT) procedures in Canada during calendar year 2024.\* Depending on the future product label approved by Health Canada, and considering the specialized nature and expected contribution of the treatment to the allo-HSCT field, Zemcelpro® (if approved by Health Canada) is expected to be an appropriate option for a significant portion of Canadian patients requiring these allo-HSCT procedures annually.

Zemcelpro® recently received conditional marketing authorization in Europe from the EC for the treatment of adults with hematological malignancies requiring an allo-HSCT procedure following myeloablative conditioning for whom no other type of suitable donor cells is

available. In addition to this first conditionally approved indication, Cordex expects to initiate, as soon as possible, an international multi-center phase 3 clinical trial in patients with high- and very high-risk acute leukemias and myelodysplasias, which is a post-authorization measure for the product's conditional marketing authorization in Europe. The phase 3 clinical trial for this second indication is expected to be completed within four years. Subject to an assessment of available regulatory pathways in Canada, Medexus intends to submit UM171 Cell Therapy for Health Canada approval as soon as possible, and no later than the successful completion of the phase 3 clinical trial by Cordex. As part of the regulatory process for UM171 Cell Therapy, Medexus intends to seek Health Canada approval of the brand name Zemcelpro®, which has not yet been reviewed or accepted by Health Canada nor approved for use in Canada. Zemcelpro® is a registered trademark of Cordex or its related companies in Canada.

"We expect that, if approved by Health Canada, Zemcelpro® will both grow our Canadian net revenues over the medium term and help us continue building our North American franchise in hemato-oncology, specifically allo-HSCT," Mr. d'Entremont continued.

"Following and subject to Health Canada approval of Zemcelpro®, our team will be ready and eager to put our institutional knowledge to work making an innovative new product in an evolving field available to healthcare professionals and patients across Canada. In the meantime, we hope that — where clinically appropriate in light of an unmet medical need — eligible patients will be able to access the product via case-by-case approvals under Health Canada's 'special access programs' for non-marketed products not yet authorized for sale in Canada."

Subject to regulatory approval and subsequent engagement with relevant Canadian payer bodies, Medexus expects that the net price of Zemcelpro® in Canada will be competitively positioned relative to other cell and gene therapy products available in Canada. Medexus's pricing analysis in advance of any commercial launch in Canada will be informed by, and subject to, the expected continued evolution of the allo-HSCT field in Canada and globally in the coming years, among other factors.

Medexus will pay to ExCellThera quarterly royalty payments on net sales of the product and various one-time milestone payments that share the potential rewards from this opportunity and align the parties' interests around long-term net revenue performance. Cordex will manage the phase 3 clinical trial and will be responsible for the manufacturing and supply of the product to Medexus on a cost-plus basis. Medexus made an initial US\$2 million payment to Cordex and has agreed to sponsor the new drug submission seeking Health Canada approval of UM171 Cell Therapy in Canada as Zemcelpro® (dorocubicel). The initial term of the license and supply agreements will extend through to the 10-year anniversary of Health Canada approval (if any) with successive two-year extension terms thereafter.

"We have readily funded the initial payment to Cordex entirely with proceeds from the delayed draw term loan feature of our senior secured credit facility with National Bank of Canada," added Brendon Buschman, Chief Financial Officer of Medexus. "We view this deal as another example of our ability to execute potentially accretive transactions that make efficient use of our capital and leverage our existing commercial infrastructure, with no significant effect on our near-term capital allocation strategy."

\* Source: *Cell Therapy Transplant Canada registry, internal data (2025).*

## **About UM171 Cell Therapy**

Zemcelpro® (dorocubicel), also known as UM171 Cell Therapy, is a novel personalized cryopreserved hematopoietic stem cell transplantation product containing two components, namely UM171-expanded CD34+ cells (dorocubicel) and unexpanded CD34- cells, each derived from the same cord blood unit.

Zemcelpro®, developed by Cordex Biologics, a wholly owned subsidiary of ExCellThera, has been evaluated in over 120 patients with hematologic malignancies in clinical trials in the United States, Europe, and Canada. The product has received orphan drug designation and regenerative medicine advanced therapy (or RMAT) designations from the US Food and Drug Administration and orphan medicinal product designation, advanced therapy medicinal product (or ATMP) classification, and priority medicines (or PRIME) designations from the European Medicines Agency.

Zemcelpro® has been tested in phase 2 clinical trials in 60 adult patients with high- and very high-risk acute leukemias (AL) and myelodysplastic syndromes (MDS) who have limited treatment options with low survival outcomes and high incidence of relapse under the current standard of care, including patients with TP53 mutations or other genetic abnormalities, patients requiring a second transplant, and patients with refractory or active disease. Positive topline results from the phase 2 clinical trials were recently announced. For more information, see "About the phase 2 clinical trials". Cordex intends to initiate a pivotal phase 3 clinical trial in this patient population in the near future.

Zemcelpro® (dorocubicel) is conditionally approved by the European Commission for sale and use in European Union member states and Iceland, Norway, and Liechtenstein only. Medexus makes no representation that Zemcelpro® is appropriate for, or authorized for sale to or use by, persons who are not located in these approved jurisdictions (such as persons who are located in Canada or the United States). The brand name Zemcelpro® has not yet been reviewed or accepted by Health Canada nor approved for use in Canada.

Medexus Pharmaceuticals Inc. holds exclusive commercial rights to UM171 Cell Therapy in Canada under June 2026 agreements with ExCellThera and Cordex Biologics. Any commercialization of the product in Canada under the brand name Zemcelpro® or otherwise is subject to the review and approval of the product and brand name by Health Canada, and there can be no assurance as to the occurrence, timing, or outcome of any such Health Canada review process.

Zemcelpro® is a registered trademark of Cordex or its related companies.

## **About the phase 2 clinical trials**

Positive topline results from phase 2 clinical trials of Zemcelpro®, also known as UM171 Cell Therapy, were recently announced. Outcomes were assessed in 60 adults with high- or very high-risk acute leukemias (AL) and myelodysplastic syndromes (MDS) who received Zemcelpro® in two prospective phase 2 trials conducted in the United States, Canada, and Europe. High-risk AL/MDS was defined as disease with an expected 2-year progression-free survival (PFS) <40% after conventional allogeneic hematopoietic stem cell transplantation (allo-HSCT). Very high-risk disease was defined as a second allo-HSCT, AL with active disease, acute myeloid leukemia (AML) with TP53 mutation and complex karyotype, AML

with EVI1 mutation, or MDS with multi-hit TP53 mutation. The primary endpoints were safety and NRM; secondary endpoints included PFS, overall survival (OS), relapse incidence, engraftment, and graft-versus-host disease (GVHD).

Sixty (60) patients (median age 43 years; range 19-66) were transplanted; 87% had AL (63% myeloid, 37% lymphoid) and 13% had MDS. Thirty percent (30%) had failed a prior allogeneic transplant and 57% met very high-risk criteria. All patients completed planned 2-3 years of follow-up.

At 24 months post-transplant, overall survival (OS), progression-free survival (PFS), and relapse-free survival (RFS) were 63.7%, 57.0%, and 60%, respectively, among Zemcelpro®-treated patients. The cumulative incidences of relapse and non-relapse mortality (NRM) were 22.5% and 20.5%, respectively. Age was the strongest predictor of NRM: patients <43 years experienced 0% NRM, with 24-month OS and PFS of 82.8% and 79.3%, respectively. Older patients (≥43 years) had comparable relapse rates but higher NRM. Grade III-IV acute GVHD occurred in 20%, while moderate to severe chronic GVHD was infrequent at 7% at two years.

## **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 hemat oncology and rheumatology and allergy. For more information about Medexus and its product portfolio, please see the company's corporate website at [www.medexus.com](http://www.medexus.com) and its filings on SEDAR+ at [www.sedarplus.ca](http://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 business strategy, outlook, and other expectations and plans

regarding financial or operational performance, including those specific to or otherwise attributable to UM171 Cell Therapy and potential related synergies or economies of scope (or other measures of strategic fit) across products, if any; the occurrence, timing, and expected outcome of a phase 3 clinical trial of UM171 Cell Therapy, a Health Canada review process for UM171 Cell Therapy (including any approvals under Health Canada's 'special access programs'), and a related commercial launch in Canada (in each case if any); the potential benefits of UM171 Cell Therapy; expectations regarding the commercialization of UM171 Cell Therapy and the product's prospects and performance, including the potential product-level net revenue to be generated (including in light of the expected cost of production and of treatment) and the product's potential adoption and use in Canada (in particular, adoption and use relative to total allo-HSCT procedures annually), its level of contribution to allo-HSCT in Canada, its contribution to Medexus's future total net revenue and operating cash flow (including the effect of agreement terms on the interests and incentives of one or more transaction parties), and its, and the company's, potential competitive position; without limiting the generality of the foregoing factor(s), Medexus's planned product pricing strategies (including its assessments of the net price of cell and gene therapy products in Canada, which will likely change from time to time as the allo-HSCT field continues to evolve, among other factors), which will be affected by Medexus's reimbursement strategies, including reimbursement coverage and reimbursement rates under government programs and trends in hospital and other institutional management of government program mechanisms, which can introduce and affect exposure to pricing risk; and uncertainty regarding, and the potential resulting effects of, the rapidly-evolving nature of the allo-HSCT field and the therapeutic area in which UM171 Cell Therapy is situated, including in respect of the size and value of any relevant product markets. 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 statements in this news release are based on assumptions regarding the following, among others: current and potential eligible patient populations and numbers of associated medical procedures (including related treatment, dosage, and other medical practices) in Canada; the current Canadian treatment landscape and current Canadian competitive dynamics, including assumptions regarding potential future changes to each; market access dynamics and the level and speed of product uptake; Medexus's planned product pricing strategies (including its assessments of the net price of cell and gene therapy products in Canada, which will likely change from time to time as the allo-HSCT field continues to evolve, among other factors); Medexus's reimbursement strategies (including reimbursement coverage and reimbursement rates under government programs) and trends in hospital and other institutional management of government program mechanisms, which can introduce and affect exposure to pricing risk; and the relevance and representativeness of the reimbursement information for the select cell and gene therapy products reviewed as referenced in this news release. The success of Medexus's planned commercial, market access, and medical strategies will depend in part on the Canadian 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 and development 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 regulatory authorities and/or other relevant third parties; and whether regulatory authorities and/or other relevant third parties will be satisfied with the design and methodology of and results from the relevant study and any regulatory review process(es), 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 safety and efficacy. 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**

This news release contains references to trademarks and other protected names and marks, including those belonging to other companies, persons, or entities. For example, Zemcelpro® is a registered trademark of Cordex or its related companies. 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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