ZemcelproÂ® (UM171 Cell Therapy) licensing and supply agreements announced for Canada

Descrizione

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COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

â?? ZemcelproÂ® (dorocubicel), also known as UM171 Cell Therapy, recently received conditional marketing authorisation in Europe from the European Commission

â?? Exclusive licensing and supply agreements have been granted to Medexus for the Canadian commercialization rights for ZemcelproÂ® (if approved by Health Canada)

MONTREAL, June 10, 2026 /PRNewswire/ â?? ExCellThera Inc. (â??ExCellTheraâ?•), a global leader in blood stem cell expansion and metabolic fitness technologies, together with its wholly owned subsidiary Cordex Biologics (â??Cordexâ?•), today announced exclusive licensing and supply agreements granting Medexus the Canadian commercialization rights for ZemcelproÂ® (dorocubicel), also known as UM171 Cell Therapy.

ZemcelproÂ® 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. The product is used to treat hematological malignancies (blood cancers), such as leukemias and myelodysplasias. Given the productâ??s current stage of development in Canada, Medexus does not expect to begin commercializing the product before calendar year 2028 (depending on available regulatory pathways). As part of the regulatory process, Medexus intends to seek Health Canada approval of the brand name ZemcelproÂ®.

â??These agreements with Medexus represent today an important milestone and reflect our continued commitment to advancing ZemcelproÂ® for patients with significant unmet medical needs,â?• said David Millette, CEO of Cordex. â??In addition to the strong commercial opportunity this partnership creates, we believe it has the potential to meaningfully improve access to innovative therapies for Canadian patients with high-risk blood cancers requiring allogeneic stem cell transplantation, where

new treatment options remain critically needed.â?•

Medexus is a leading specialty pharmaceutical company with extensive experience in hematology and oncology, making it a strong strategic fit for the partnership with Cordex.

Importantly, this agreement also represents a broader step forward in Cordexâ??s global commercialization strategy for ZemcelproÂ®. Cordex continues to actively pursue additional strategic partnerships to support and accelerate the commercialization of ZemcelproÂ® across Europe and other international markets.

â??We believe there is substantial global interest in innovative therapies that address persistent unmet needs in blood malignancies and conventional stem cell transplantation, and we remain focused on identifying partners with the expertise, infrastructure, and shared vision necessary to expand patient access worldwide,â?• said David Millette. â??As we advance these discussions, our priority remains clear: bringing innovative and potentially life-changing therapies to patients who urgently need new treatment options while creating long-term value for our stakeholders.â?•

The transaction includes royalties on Canadian net sales and milestone payments, creating a shared economic interest in the productâ??s long-term commercial success. Cordex will continue to manage the clinical program and will be responsible for the manufacturing and supply of ZemcelproÂ® to Medexus.

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About ZemcelproÂ®

ZemcelproÂ® (dorocubicel), also known as UM171 Cell Therapy, is a novel personalized cryopreserved haematopoietic 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.

ZemcelproÂ® has recently received conditional marketing authorization from the European Commission for the treatment of adults with haematological malignancies requiring allogeneic haematopoietic stem cell transplantation following myeloablative conditioning, for whom no other suitable donor cells are available. For complete product information, including warnings and precautions for use and adverse reactions (and their appropriate management), please refer to the EU Summary of Product Characteristics (SmPC) for ZemcelproÂ®.

Additional regulatory filings are planned for ZemcelproÂ® with other health authorities, including in the US, Canada, the UK, and Switzerland.

ZemcelproÂ® has been evaluated in over 120 patients with haematologic malignancies in clinical trials in the United States, Europe and Canada. ZemcelproÂ® has received orphan drug designation and regenerative medicine advanced therapy (RMAT) designations from the FDA as well as orphan medicinal product designation, advanced therapy medicinal product (ATMP) classification and priority medicines (PRIME) designation from the EMA.

ZemcelproÂ® has been tested in Phase 2 trials in patients with high- and very high-risk acute leukemias and myelodysplasias who have limited treatment options with low survival outcomes and

high incidence of relapse under the current standard of care, including patients with patients with TP53 mutations or other genetic abnormalities, patients requiring a second transplant, and patients with refractory or active disease. A pivotal Phase 3 trial in this patient population will be initiated as soon as possible.

The use of ZemcelproÂ® in other patient populations, including pediatric patients and patients with non-malignant haematological diseases, is also being investigated.

The product safety and efficacy have not yet been established by other regulatory agencies, such as the U.S. FDA, the MHRA and Health Canada.

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. Medexusâ??s current focus is on the therapeutic areas of hematology and hemato-oncology and rheumatology and allergy. For more information about Medexus and its product portfolio, please see the companyâ??s corporate website at www.medexus.com and its filings on SEDAR+ at www.sedarplus.ca.

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About ExCellThera and UM171 Technology

ExCellThera is a world leader in enhanced blood stem cell therapies. ExCellTheraâ??s proprietary EnhanceTM platform for cell expansion and metabolic fitness is designed to deliver a greater dose of functional therapeutic stem cells by expanding haematopoietic stem cells (HSCs) from any source and counteracting the effects of culture or gene editing induced stress. ExCellThera partners with biopharmas to help them develop best-in-class cell and gene therapies by leveraging the technologies that form the EnhanceTM platform, including the proprietary molecule UM171 which has a first-in-class mechanism of action for ex vivo expansion and metabolic fitness of HSCs. For additional information, visit excellthera.com, and follow us on LinkedIn.

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

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View original content to download multimedia:https://www.prnewswire.co.uk/news-releases/zemcelpro-um171-cell-therapy-licensing-and-supply-agreements-announced-for-canada-302795989.html

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