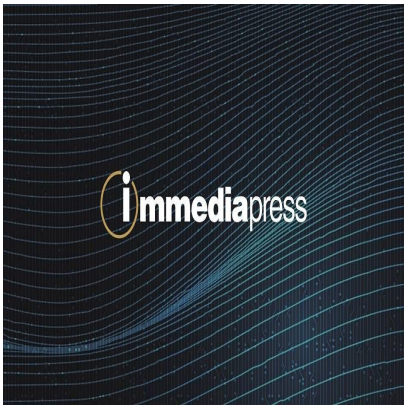

ZemcelproÂ® (dorocubicel) Positive Results in High- and Very High-Risk Blood Cancers to be Reported at the EBMT 2026 Annual Meeting

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

MONTREAL, March 10, 2026 /PRNewswire/ â?? ExCellThera Inc. (ExCellThera), a world leader in blood stem cell expansion and metabolic fitness, and its wholly owned subsidiary Cordex Biologics (Cordex), announce positive results from recently completed Phase 2 studies of ZemcelproÂ® (dorocubicel), also known as UM171 Cell Therapy, in 60 adult patients with high- and very high-risk acute leukemias (AL) and myelodysplastic syndromes (MDS), a population known to experience high relapse rates and poor survival on conventional allogeneic stem cell transplantation (allo-HSCT). Topline results will be presented on March 23, 2026 at the 52nd EBMT Annual Meeting in Madrid, Spain.

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 ZemcelproÂ® (dorocubicel)-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 (â?¥43 years) had comparable relapse rates but higher NRM. Grade III-IV acute graft-versus-host disease (GVHD) occurred in 20%, while moderate to severe chronic GVHD was infrequent at 7% at two years.

â??This represents a remarkable and clinically meaningful achievement for ZemcelproÂ® (dorocubicel), especially given the historical overall survival of only 25â??40%1 for patients of similar disease risk receiving standard of care allogeneic grafts,â?• said Dr Guy Sauvageau, Chief Scientific Officer. â??Results are particularly promising in adults under 43 years of age, showing even greater benefits in both OS and PFS, with no cases of NRM.â?•

â??These findings suggest that ZemcelproÂ® (dorocubicel) could redefine the standard of care for patients with high- and very high-risk blood cancers,â?• said David Millette, CEO. â??Based on its safety and efficacy profile, this positions ZemcelproÂ® (dorocubicel) as a potentially transformative therapy, challenging the existing treatment paradigm and offering renewed hope for difficult-to-cure

high- and very high-risk patients facing unfavorable outcomes with conventional approaches.â?•

About the studies

Outcomes were assessed in 60 adults with high- or very highâ??risk AL or MDS who received ZemcelproÂ® (dorocubicel) 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 PFS <40% after conventional 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, OS, relapse incidence, engraftment, and GVHD.

Sixty (60) patients (median age 43 years; range 19â??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.

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® (dorocubicel) 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® (dorocubicel).

Additional regulatory filings are planned for ZemcelproÂ® (dorocubicel) with other health authorities, including in the US, Canada, the UK, and Switzerland. Cordex is also actively seeking strategic partnerships to support and accelerate the commercialization of ZemcelproÂ® (dorocubicel) in Europe and other international markets.

ZemcelproÂ® (dorocubicel) has been evaluated in 120 patients with haematologic malignancies in clinical trials in the United States, Europe and Canada. ZemcelproÂ® (dorocubicel) 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® (dorocubicel) 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® (dorocubicel) 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 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 ExCellThera or its related companies.

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Armand P, Kim HT, Logan BR, Wang Z, Alyea EP, Kalaycio ME, et al. Validation and refinement of the Disease Risk Index for allogeneic stem cell transplantation. Blood. 2014;123(23):3664â??367

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https://mma.prnewswire.com/media/2928711/ExCellThera_Zemcelpro_%C2%A0_dorocubicel__Positive_

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