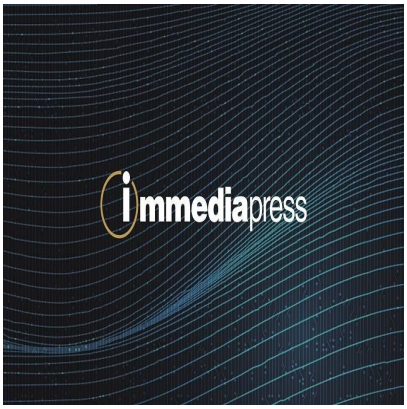

ZemcelproÂ® (dorocubicel) receives NUB Status 1 in Germany

Descrizione

default watermark

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

MONTREAL, Feb. 16, 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), announced that ZemcelproÂ® (dorocubicel), also known as UM171 Cell Therapy, has been granted Status 1 listing by the NUB (Neue Untersuchungs- und Behandlungsmethoden) program in Germany.

The NUB designation is a recognition that ZemcelproÂ® (dorocubicel) is supported by a relevant and growing body of clinical evidence and enables hospitals to immediately apply for temporary, supplementary reimbursement for its use while broader reimbursement pathways continue to be evaluated. Notably, 220 hospitals across Germany have expressed interest in accessing ZemcelproÂ® (dorocubicel) through the NUB mechanism for the 2026 calendar year.

â??NUB Status 1 represents a significant milestone for ExCellThera and Cordex and reflects both the innovative nature of ZemcelproÂ® (dorocubicel) and its benefit in in addressing a pressing unmet medical need in allogeneic haematopoietic stem cell transplantation,â?• said David Millette, CEO of ExCellThera. â??Under its initial label, ZemcelproÂ® (dorocubicel) is indicated for patients with life threatening blood cancers who have limited therapeutic options.â?•

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.

With NUB status 1 in place for ZemcelproÂ® (dorocubicel), Cordex will work closely with leading German stem cell transplant centers to support individual NUB applications and to further expand clinical adoption. In parallel, the company will invest in post-market registry participation, and in evidence and economic data generation to support longer-term reimbursement and inclusion of ZemcelproÂ® (dorocubicel) in clinical guidelines. Together, these elements strengthen ZemcelproÂ® (dorocubicel)â??s commercial foundation in Germany and provide a constructive bridge toward future

statutory reimbursement by the healthcare system.

The availability of ZemcelproÂ® (dorocubicel) in individual European countries depends on several factors, including completion of national reimbursement procedures. In the interim, Cordex will engage with national health authorities to enable early access for eligible patients and is engaging with leading stem cell transplantation centres to establish a future network of treatment sites for ZemcelproÂ® (dorocubicel) administration.

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.

About ZemcelproÂ®

default watermark

ZemcelproÂ®, 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), developed by Cordex, a wholly owned subsidiary of ExCellThera, 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.

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®.

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.

Logo â??
https://mma.prnewswire.com/media/2904398/ExCellThera_Zemcelpro___dorocubicel__receives_NUB_St

View original content:https://www.prnewswire.co.uk/news-releases/zemcelpro-dorocubicel-receives-nub-status-1-in-germany-302688429.html

Copyright 2026 PR Newswire. All Rights Reserved.

default watermark

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE: Immediapress Ã¨ un servizio di diffusione di comunicati stampa in testo originale redatto direttamente dallâ??ente che lo emette. Lâ??Adnkronos e Immediapress non sono responsabili per i contenuti dei comunicati trasmessi

â??

immediapress/pr-newswire

Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Febbraio 16, 2026
Autore
redazione