

press release



Glycostem initiates phase I/Ila (pivotal) trial to evaluate the safety and efficacy of oNKord® in patients with Acute Myeloid Leukemia (AML)

20th November 2020, Oss, the Netherlands November – Glycostem Therapeutics B.V., a leading clinical-stage company focused on the development of therapeutic off-the-shelf Natural Killer (NK) cells, today announced the opening of a phase I/Ila trial for its lead product oNKord® for the treatment of AML patients. The WiNK trial will enroll 33 AML patients at eight clinical sites based in five European countries. oNKord® is the company's first-generation off-the-shelf allogeneic NK cellular immunotherapy product. Glycostem is furthermore developing a range of second (CAR-NK) and third generation (TCR-NK) NK products in-house.

“During our phase I safety study, in which ten elderly AML patients were treated, we verified our lead product oNKord® to be a safe therapeutic agent in the field of cellular immunotherapy. Interestingly, year 1 survival data showed promising efficacy outcome (80%) compared to historical cohort data (40%),” tells Troels Jordansen, CEO at Glycostem. “The opening of this phase I/Ila / pivotal trial is an important step and we are looking forward to the data from this study, which will allow us to draw conclusions regarding oNKord® safety and tolerability and most importantly its efficacy for treatment of AML patients.”

Professor Doctor Arnold Ganser, MD of Hannover Medical School in Germany and WiNK trial coordinating investigator said: “The preliminary efficacy data obtained with oNKord® was very promising and NK-cells have proven to be highly capable of targeting cancer cells. Therefore, I am excited about participating and being able to enroll patients in the WiNK trial.” He continues: “Currently there is a risk of relapse for 80% of the successfully treated patients. This new form of cellular treatment can change the lives and future prospects of many patients with AML worldwide who do not proceed to allogeneic hematopoietic stem cell transplantation, in particular elderly patients, who represent the majority of patients with AML.”

WiNK is a prospective two-stage, open-label, single arm, multicenter phase I/Ila trial to evaluate the safety and efficacy of oNKord®, an off-the-shelf, ex. vivo-cultured allogeneic NK cell preparation, in 33 adults with AML who are in complete morphologic remission with residual measurable disease and with no strong indication for hematopoietic stem cell transplantation.

A full description of the [WiNK trial](#) is published on www.clinicaltrial.gov.

About Glycostem

Netherlands-based Glycostem Therapeutics B.V., a clinical stage biotech company, develops allogeneic cellular immunotherapy to treat several types of cancer. By harnessing the power of stem cell-derived Natural Killer (NK) cells, Glycostem's products are a safer alternative to CAR-T-cells. Glycostem's lead

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product, oNKord®, is manufactured from allogeneic raw material and is available off-the shelf. Thanks to its nine patent families, longstanding technical expertise and resources, as well as ‘Orphan Drug Designation’, Glycostem has secured a leadership position in the global NK-cell market.

oNKord® is produced in a closed system in Glycostem’s state-of-the-art and GMP (Good Manufacturing Practice) licensed production facility in the Netherlands, from which it can be distributed globally. The production technology includes *ex vivo* generation of high numbers of NK cells with a high degree of purity for clinical applications. oNKord® successfully passed phase I clinical trial (elderly and frail AML patients), providing solid safety data and strong indication of clinical activity, including response on MRD (Minimal Residual Disease). Results indicate that oNKord® may be safely infused in AML patients.

Glycostem is furthermore developing a range of CAR-NK and TCR-NK products in-house and in cooperation with global partners.

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