

## Glycostem announces initial clinical data to be presented at 2021 ASH Annual Meeting

- **Clinical data of the first two acute myeloid leukemia patients enrolled in the phase I/IIa WiNK clinical trial to be presented at the 63rd American Society of Hematology meeting**
- **Clearance of measurable residual disease seen in one patient for 6 months and in the second patient for 1 month after a single infusion of oNKord®, an off-the-shelf NK cell immunotherapy, in the lowest dose cohort**

**Oss, the Netherlands – 4<sup>th</sup> November 2021** – Glycostem Therapeutics B.V., a leading clinical-stage company focused on the development of therapeutic allogeneic off-the-shelf Natural Killer (NK) cells, today announced that the abstract on the initial findings of the first two patients treated in its phase I/IIa WiNK trial have been accepted and will be presented at the 63<sup>rd</sup> American Society of Hematology Annual Meeting and Exposition (ASH 2021), which will take place 11<sup>th</sup> – 14<sup>th</sup> December 2021 in Atlanta, GA, USA. oNKord® is the company's first-generation off-the-shelf allogeneic NK cell therapy under clinical development. Glycostem is furthermore developing a range of CAR-NK, combination therapy and TCR-NK products in-house.

The accepted abstract is published today and available on the ASH website: [www.hematology.org](http://www.hematology.org).

Title: Allogeneic, CD34+, Umbilical Cordblood-Derived NK Cell Adoptive Immunotherapy for the Treatment of Acute Myeloid Leukemia Patients With Measurable Residual Disease

Abstract #: 1745

Session Name: 704. Cellular Immunotherapies: Clinical: Poster I

Date: Saturday, 11<sup>th</sup> December 2021

Presentation Time: 5:30 PM - 7:30 PM (EST)

Location: Georgia World Congress Center, Hall B5, Atlanta, GA, USA

“We are very excited to share the first clinical data from our WiNK phase I/IIa trial of oNKord® in patients with Acute Myeloid Leukemia. We are very pleased to see that these first positive results with a single dose infusion with our off-the shelf and allogeneic NK cell product, are confirming our observations from our past clinical trial,” said Kai Pinkernell, MD, Chief Medical Officer of Glycostem.

- The first patient converted to measurable residual disease (MRD) negativity (<0.1%) as assessed by multiparametric flowcytometry (MFC) on bone marrow on day 0, which was sustained at 1, 2, 3 and 6 months. NPM1 MRD, which was detectable by next

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generation sequencing (MRD-NGS) up to month 1 in peripheral blood (PB), became undetectable by month 2, 3 and 6 in PB (<0.01%VAF). Results in BM showed that NPM1 MRD was detectable at month 1 but was cleared at months 3 and 6.

- The second patient showed MRD positivity in BM by MFC at screening and on day 0, which turned to MRD negativity at month 1, turning positive again at month 2 and 3. Assessments in PB and BM by MRD-NGS showed that a IDH2 and a SRSF2 clone persisted after preconditioning and GTA002 infusion, but that a PTPN11 clone became undetectable in PB by Day 0 and in BM by month 2 and month 3.
- The most recent available follow up will be presented at time of presentation.

## About Glycostem

Netherlands-based Glycostem Therapeutics B.V., a clinical stage biotech company, developing allogeneic cellular immunotherapies to treat several types of cancer, by harnessing the power of stem cell-derived Natural Killer (NK) cells. NK cells have been shown to mediate graft-versus-leukemia (GVL) immunity towards recipient tumor cells without attacking recipients' normal tissues, which would otherwise lead to graft-versus-host disease (GVHD).

Glycostem's lead product, oNKord<sup>®</sup>, is manufactured from allogeneic raw material and is available off-the-shelf, cryopreserved. 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 with off-the-shelf products.

Beside of oNKord<sup>®</sup>, Glycostem is developing a range of CAR-NK and TCR-NK products in-house and in cooperation with global partners.

## About oNKord<sup>®</sup>

oNKord<sup>®</sup> is the company's first-generation Natural Killer (NK) cell-based immunotherapy product in clinical development. It gets produced in a closed system (uNiK<sup>™</sup>) 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 derived feeder cell free from umbilical cord blood, with a high degree of purity for clinical applications.

## About the WiNK clinical trial

The WiNK trial ([NCT04632316](https://clinicaltrials.gov/ct2/show/study/NCT04632316)) is a phase I/II clinical trial Glycostem to evaluate the safety and efficacy of oNKord<sup>®</sup> in patients in completed remission, who have AML and MRD and are not undergoing hematopoietic stem cell transplantation. The clinical trial intends to enrol 33 AML patients at eight clinical sites based in five European countries. oNKord<sup>®</sup> successfully passed a phase I clinical trial (elderly AML patients), providing safety data and first signs of clinical activity, including responses on MRD.

oNKord<sup>®</sup> is a registered trademark of Glycostem in the US and Europe. viveNK<sup>™</sup> and uNiK<sup>™</sup> are pending trademarks of Glycostem.

## Glycostem Therapeutics BV

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