press release

Glycostem announces treatment of first patient in pivotal phase I/IIa trial of oNKord® in patients with Acute Myeloid Leukemia

Dosing of the first of 33 adult patients with AML who are in complete morphologic remission with measurable residual disease and with no strong indication for hematopoietic stem cell transplantation

Oss, the Netherlands – 15th December, 2020 – Glycostem Therapeutics B.V., a leading clinical-stage company focused on the development of therapeutic off-the-shelf Natural Killer (NK) cells, today announced that the first patient has been dosed in its pivotal phase I/IIa trial of oNKord® for the treatment of Acute Myeloid Leukemia (AML). 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.

"We are thrilled about the first patient being dosed in this pivotal trial. This important milestone potentially paves the way for a positive impact on the lives of patients with AML who are at high risk of relapse. The preliminary efficacy data obtained with oNKord® is very promising 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," tells Troels Jordansen, CEO at Glycostem.

"We are very excited about being involved in the WiNK trial and to learn what the efficacy of oNKord® will be on eradicating measurable residual disease (MRD) in AML patients," tells Professor Heuser, Investigator and Head of the central laboratory for MRD assessment at the Hannover Medical School in Germany. "Currently, two thirds of MRD-positive AML patients who are in complete morphologic remission will relapse, and unfortunately, there is no cure for this group of patients if allogeneic stem cell transplantation is not an option. Therefore, the outcome of this trial is literally of vital importance and positive results could have a very significant impact on the prospects of current and future patients we are treating."

Evaluating safety, tolerability and efficacy

WiNK (ClinicalTrials.gov identifier: NCT04632316) is a prospective two-stage, open-label, single arm, multicenter phase I/IIa 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.

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Stage A of the trial is designed to assess the safety and tolerability of escalating doses of oNKord® in three cohorts of three subjects each. An Independent Data Monitoring Committee (IDMC) will review safety data of all treated subjects in each cohort and make recommendations before moving to the next dose. Stage B of the trial will enroll an additional 24 subjects to evaluate the safety, tolerability and efficacy of oNKord® at the recommended phase II dose, as identified from stage A.

About Glycostem

Netherlands-based Glycostem Therapeutics BV, 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 safe alternative to CAR-T-cells. Glycostem's lead 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 -Acute Myeloid Leukemia -patients), providing solid safety data and strong indication of clinical activity, including response on MRD (Measurable 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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