

FOR IMMEDIATE RELEASE

25th June 2019

Glycostem receives GMP license for oNKord®

25th June 2019, Oss, The Netherlands — Glycostem Therapeutics BV today announced they have received GMP license for Glycostem’s proprietary closed production system used to manufacture their lead product, oNKord®, an off-the-shelf, allogeneic Natural Killer (NK) cell therapy.

Troels Jordansen, CEO said “This is a key milestone for Glycostem as it allows us to progress with our pivotal clinical trials in Acute Myeloid Leukemia (AML) to be followed by Multiple Myeloma (MM), two life-threatening hematologic malignancies with severe prognostic. But it is also a unique event in the cellular therapy sector as this is the first inspection leading to approval of a closed allogeneic cellular production system in a class-C cleanroom. This major achievement allows for oNKord® production in class-C clean room which is more cost efficient than in class-A/B clean rooms; both in set-up and running costs.”

oNKord® is an off-the-shelf product of NK-cells generated *ex vivo* from umbilical cord blood (UCB) and is an investigational product aiming at registration as Advanced Therapy Medicinal Product for use in immune oncotherapy. NK-cells are known for not inducing GvHD or cytokine storm, so a safe alternative to other cellular products. Multiple patients can currently be



Contact:

Troels Jordansen +31 6 1834 5326 - Troels@Glycostem.com – www.Glycostem.com

treated with a batch from one UCB donor, moreover planned automation steps and process improvements suggest to significantly reduce production costs and increase cell yields. This will drive down the production cost to a fraction of that of CAR-T-cell products. Glycostem expects to start the above mentioned multicenter (8 sites) AML trial in 5 European countries in Q1 '20.

- end -

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.

oNKord[®] is produced in a closed system in Glycostem's state-of-the-art production facility in the Netherlands, from which it can be distributed globally. The production technology includes *ex vivo* generation of high numbers of activated NK-cells with a high degree of purity for clinical applications. The lead product, 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. Results indicate that oNKord[®] may be safely infused in patients with AML patients.

Thanks to its eight 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.



Contact:

Troels Jordansen +31 6 1834 5326 - Troels@Glycostem.com – www.Glycostem.com