

Glycostem Therapeutics and Autolomous announce commercial contract to digitise Glycostem’s manufacturing process to expedite delivery of NK-cell therapies

London, UK and Oss, the Netherlands, June 3rd, 2020 – Autolomous Ltd, a leading edge developer of innovative digital solutions for manufacture of advanced medicines, and Glycostem Therapeutics BV, a clinical stage and leading Natural Killer (NK) cell manufacturing company, today announce the intended implementation of the AutoloMATE platform to digitise the manufacturing and release of Glycostem’s NK-cell therapies for clinical trials and beyond.

“This is an excellent development for Autolomous as we seek to extend our portfolio of users across Europe and the USA and the diversity of products we can support. Glycostem shares our vision of high quality, cost-effective supply chains for cellular medicines and has developed a sophisticated manufacturing process for NK-cells from umbilical cord blood. This is the first application of the AutoloMATE platform to an allogeneic process which is particularly exciting for us”, said Alexander Seyf, CEO of Autolomous

Autolomous will be implementing the AutoloMATE platform to meet the needs of Glycostem’s allogeneic NK-cell manufacturing process. Driving efficiency throughout the capturing / review and release of manufacturing data. Leveraging leading edge technologies such as distributed ledger technologies, IoT and AI.

“At Glycostem we went through a detailed and comprehensive procurement process with many potential suppliers before final selection of Autolomous as our chosen provider. The AutoloMATE platform will be tailor-made for the manufacturing process in our state-of-the-art in-house facility. The broad experience of the Autolomous team gave us confidence in delivery of the product on time to meet our ambitious clinical development schedule and route to the market”, said Troels Jordansen, CEO of Glycostem.

Glycostem expects to start its pivotal clinical trial in AML in 2nd half '21 in 5 different European countries and 8 clinical centres. It will be the first off-the-shelf cellular immunotherapy NK-cell product entering pivotal trials.

About Autolomous

Autolomous is a company founded by Cell and Gene Therapy (CGT)- and software development experts, who have combined their skills to deliver elegant solutions to the CGT sector. Autolomous will deliver the digital solutions necessary for CGT to achieve scalability, allowing more patients to benefit from these life changing therapies. The company is creating a portfolio of software solutions (AutoloMATE), from electronic Batch Manufacturing Records (eBMR) to enabling the scheduling of the patient blood collections at hospital; the transport of those cells to the manufacturing facilities; enhancing traceability throughout the manufacturing process; supporting compliance with current and future regulatory requirements; expediting the drug product release; and the scheduled delivery of the patient-

specific medicine to the hospital. Our software will enable increased automation of these processes, reducing the risk of errors and ensuring that the correct product is returned to the right patient.

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 (Minimal Residual Disease). Results indicate that oNKord[®] may be safely infused in AML patients. Glycostem is furthermore developing a range of CAR-NK/TCR-NK products in-house and in cooperation with amongst other global partners.

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