



PRESS RELEASE

MolMed and Glycostem announce the execution of a binding term sheet for the development and manufacturing of allogeneic CAR-NK therapies

The agreement will allow MolMed to enlarge its proprietary oncology pipeline entering the field of CAR-NK by leveraging Glycostem technology platform

Milan (Italy), May 31st 2018 – MolMed S.p.A. (MLMD.MI), medical biotechnology company focusing on research, development, manufacturing, and clinical validation of Cell & Gene therapies to treat cancer and rare diseases, and the Dutch bio-pharmaceutical company Glycostem, operating in the clinical development of cellular allogeneic products for antitumor immunotherapy based on NK cells (“Natural Killer cells”), announce that they signed today a binding term sheet for the development and manufacturing of new NK cells–based allogeneic CAR (Chimeric Antigen Receptors).

NK cells are cells of the innate immune system, capable to mediate anti-cancer effects without the risk of inducing graft-versus-host disease (GvHD)¹. Therefore, NK cells are well suited as off-the-shelf therapy capable, starting from a single batch produced by a healthy donor, to treat a large number of patients with cancer. Under this profile, off-the-shelf CAR-NK-cells is one of the most promising and desirable cellular immunotherapy platforms, able to overcome the limitations deriving from personalized autologous therapies with significant benefits from both a technical and economical point of view. As a result CAR-engineered NK cells are today one of the most attractive and innovative pre-clinical investigations in cellular immunotherapy.

The Master Agreement will be finalized by September 30th, 2018, subject to the positive outcome of the due diligence conducted by MolMed.

According to the agreement, Glycostem and MolMed will collaborate on an exclusive base in developing and manufacturing engineered NK cells targeted to three tumor antigens: Glycostem will be responsible for the final product GMP manufacturing and release, while MolMed will have exclusive rights for the exploitation of the resulting products and Glycostem will receive upfront payments, milestones and royalties on the developed products.

Riccardo Palmisano, MolMed CEO, commented: *“The partnership with Glycostem, a pioneer and expert company with a proprietary allogeneic NK platform, represents a first, relevant step in pursuing our strategy of significantly enlarging our proprietary CAR pipeline. While our first autologous CAR T therapy is*

¹ Graft-versus-host disease (GvHD) is an immune-mediated disease resulting from a complex interaction between donor and recipient adaptive immunity



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*approaching the first phase I/II clinical trial, with this new project, MolMed is going to **expand its capabilities** to the high potential field of allogeneic therapies, leveraging on its unparalleled expertise in cell and gene therapies and on Glycostem innovative platform technology in umbilical cord derived NK cells. In developing these off-the-shelf therapies of new NK cells-based allogeneic CAR, MolMed will be able to confirm its innovative approach, generating new and original therapies, aimed to combine clinical efficacy and safety with scalable and therefore more sustainable products”.*

Troels Jordansen, Glycostem CEO, commented: “We are very proud to be teaming up with one of the most innovative cellular therapy companies around and jointly develop mold-breaking products for the help of doctors and patients. The synergy between MolMed and Glycostem is tangible and we are confident it could lead to exciting results in the short term. This is also the initiation of Glycostem’s in-house development program in our new state-of-the-art facility in the Netherlands. It is out of the same facility that we expect to have GMP approval for our closed-system production system by the end of 2018. This will allow us to expand our clinical trial program and enter pivotal for oNKord® early 2019.”

About MolMed

MolMed S.p.A. is a biotechnology company focused on research, development, manufacturing and clinical validation of innovative anticancer therapies. MolMed's product portfolio includes proprietary anti-tumor therapies in clinical and preclinical development: Zalmoxis® (TK) is a cell therapy based on donor T cells genetically engineered to enable bone marrow transplants from partially compatible donors for patients with high-risk hematological malignancies, eliminating post-transplant immunosuppression prophylaxis and inducing a rapid immune reconstitution. Zalmoxis® received Orphan Drug Designation and is currently in Phase III in a high-risk population of acute leukemia patients, but has already obtained a Conditional Marketing Authorization by the European Commission in the second half of 2016 as well as reimbursement conditions in Italy at the end of 2017 and in Germany at the beginning of 2018. Still focusing on this cell & gene technology, the company is developing a therapy based on Chimeric Antigen Receptor (CAR), specifically the CAR-T CD44v6, an immune gene therapy project, currently in advanced preclinical development, potentially effective for hematological malignancies and several solid epithelial tumors. MolMed is also the first company in Europe to have obtained the GMP manufacturing authorization for cell & gene therapies for its proprietary products (Zalmoxis®) as well as for third parties and/or in partnership (Strimvelis, a GSK gene therapy for the ADA-SCID). With reference to GMP development and manufacturing activities for third parties, MolMed signed numerous partnership agreements with leading European and US companies. In the framework of innovative anticancer therapies, MolMed’s pipeline also includes NGR-hTNF, a therapeutic agent for solid tumors investigated in a broad clinical program, involving more than 1,000 treated patients. MolMed, founded in 1996 as an academic spin-off of the San Raffaele Scientific Institute, is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana since March 2008. MolMed is headquartered and based in Milan, at the San Raffaele Biotechnology Department (DIBIT) and has an operating unit at OpenZone in Bresso.



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About Glycostem

Netherlands-based Glycostem Therapeutics BV, a clinical stage and privately held biotech company focused on developing off-the shelf allogeneic cellular immunotherapy using Natural Killer (NK) cells to treat several types of cancer. NK-cells are the body's first line of defence because of the innate ability of NK-cells to rapidly and accurately identify and destroy cells under stress, such as cancer or virally-infected cells.

Glycostem's lead product, oNKord®, is produced in a closed system in Glycostem's state-of-the-art production facility in The Netherlands, from which the product can be distributed globally. The platform technology includes ex vivo expansion of a high number of pure and highly activated NK-cells for clinical applications. oNKord® successfully concluded phase I clinical trial (elderly and fragile AML patients), providing solid safety data and strong indication of clinical activity, including response on MRD. Glycostem expects to obtain GMP certification by the end of 2018 and is planning to enter pivotal clinical trial in Q1 2019.

Thanks to a solid patent portfolio, longstanding technical expertise and resources, as well as 'Orphan Drug Designation', Glycostem has secured a leadership position in the global NK-cell market.

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