PRESS RELEASE

MolMed and Miltenyi Biotec: EMA approves the utilization of the CliniMACS Prodigy® equipment in the commercial manufacturing process of Zalmoxis®, a patient-specific cell therapy for the treatment of adult patients affected by leukemia and other high-risk hematological malignancies.

Milan (Italy) – Bergisch Gladbach (Germany), February, 26th 2018 – MolMed S.p.A. (MLMD.MI) a medical biotechnology company focusing on research, development, manufacturing, and clinical validation of innovative therapies to treat cancer, and Miltenyi Biotec GmbH, a global supplier of equipment and services for cell and gene therapy, announce that the European Medicines Agency (EMA) has approved the utilization of the CliniMACS Prodigy®, a closed environment, automated cell production device developed by Miltenyi Biotec, in the GMP manufacturing of Zalmoxis®.

With the positive outcome of the request submitted by MolMed to EMA, CliniMACS Prodigy® for the first time, becomes part of a manufacturing process for a commercial drug, namely Zalmoxis®, which has been authorized for marketing in Europe.

Zalmoxis®, MolMed patient-specific cell therapy, is based on engineering of the donor immune system, in combination with haplo-identical haematopoietic stem cell transplant (haplo-HSCT) for the treatment of leukemia at high-risk of relapse. This therapy is part of the immuno-oncology field that uses modified T-cells to maximize the antitumor effect of the immune system, and is considered one of the most promising frontiers in the treatment of patients suffering from malignancies refractory to conventional therapies.

Zalmoxis® was approved for commercial use by the European Community in 2016 and is reimbursable in Germany and also, from March 1st, in Italy.

The CliniMACS Prodigy® System, developed and distributed by Miltenyi Biotec, is today the only instrument in the world able to offer integrated solutions that standardize cell engineering in a completely automated process. The CliniMACS Prodigy® guarantees maximum efficiency in compliance with in-process control (IPC) and quality control (QC), both fundamental requirements for reliable cell manufacturing.

With the CliniMACS Prodigy® instrument in its GMP facility, MolMed is able to optimize the efficiency of the Zalmoxis® manufacturing cycle, in terms of doses obtained from a single production cycle, and to reduce the number of open handling steps, ensuring a reproducibly high-quality standard.

Riccardo Palmisano, CEO of MolMed, commented: "*The use of a cutting-edge production technology such as the CliniMACS Prodigy® 'confirms the qualitative excellence that differentiates MolMed in the manufacture of gene and cell therapies. By supporting the provision of a drug on the market, it enhances our potential in ensuring the availability of* Zalmoxis® *for all the patients prescribed with it. Our GMP facility will in fact produce the doses necessary for treatments in a more efficient way, while improving the quality and reliability of the process and providing a better service for the patient*".

Boris Stoffel, Miltenyi Biotec CEO, commented: "*The EMA approval is an important step for us. This is the first time that a commercial product has been approved for production on our ground-breaking cell processing platform, the CliniMACS Prodigy®. Together with our partner MolMed, we have come a long way from using our device in numerous clinical trials all over the world to using it in a commercial manufacturing process that requires a whole new level of standardization, reproducibility, and production volume. We are proud that by utilizing our technology, MolMed is able to enhance the quality and reliability of their novel cell therapy*."

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.

About Miltenyi Biotec

Miltenyi Biotec's global team of over 2,000 employees design, develop, manufacture, and market products that help advance biomedical research and enable cell and gene therapy programs.

With headquarters in Bergisch Gladbach, Germany and dedicated manufacturing facilities in Germany and the US, we supply the world with flow cytometry analyzers and sorters, instrumentation for clinical applications, cell culture devices, reagents, and cell separation technologies.

GMP-grade suites for in-house and contracted manufacturing of cell products and lentiviral vectors are integral parts of our European and North American sites.

Miltenyi Biotec's engineers, scientists, clinicians, and support teams are all dedicated to helping improve human lives. It is their know-how that is at the root of our product innovation, long-term growth, and worldwide success.

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