PRESS RELEASE

# *MolMed: the protocol of the in-man trial on CAR T CD44v6 presented at EHA (European Hematology Association) in Paris.*

Paris (France), 15th February 2019 – MolMed S.p.A. (MLMD.MI) ("the Company"), clinical stage biotechnology company focusing on research, development, manufacturing, and clinical validation of cell & gene therapies to treat cancer and rare diseases and coordinator of the EURE CART project, announces that today Professor Fabio Ciceri, Director of the Hematology and Bone Marrow Transplantation Unit (UTMO) of the San Raffaele Hospital of Milan, and principal investigator of the study, will illustrate phase I/II clinical trial protocol with CAR T CD44v6 for the treatment of patients with acute myeloid leukemia and multiple myeloma within the 1st European CAR T Cell Meeting, organized in Paris by the European Hematology Association (EHA).

Although some progress has been made in the treatment of these serious haematological malignancies, an adequate therapeutic solution is in fact not available yet. The use of CAR T cells could represent a winning strategy for both eradicating neoplastic cells in case of relapse after chemotherapy or as a "bridge" towards hematopoietic stem cell transplantation.

Most of the clinical studies conducted so far have used CAR19 antigen-specific CARs, while this study will use CAR T CD44v6 which, thanks to its own original CD44v6 receptor, is characterized by the ability to target both haematological and solid tumors, as well as by a higher promise of safety in use thanks to the insertion of the suicide gene.

The aim of the clinical study on CAR T CD44v6 presented today in Paris, is to define the safety profile of the therapy in a first step, to then identify the appropriate effective dose in a group of adults and paediatric patients.

The first phase of the trial will involve San Raffaele Hospital in Milan and Bambin Gesù Hospital in Rome, and will be then extended to other 3 European centers. The clinical investigation on the CAR T CD44v6 is in fact part of the EURE-CART project which obtained a grant of about Euro 6 million from the European Commission and involves a consortium of nine partners from five different European countries.

Professor Fabio Ciceri commented: "*We are confident of being able to bring soon to patients a new therapeutic tool that is the result of Italian Research. Thanks to European funding and Molmed's development capabilities, we have the opportunity to experience new hope for patients with acute myeloid leukemia and multiple myeloma*".

## *About MolMed*

MolMed S.p.A. is a clinical stage biotech company focused on research, development, manufacturing and clinical validation of innovative therapies. MolMed's product portfolio includes proprietary anti-tumor therapies in both 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® that 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 and in Germany at the beginning of 2018. Still focusing on this cell & gene technology, the Company is developing a new therapeutic platform based on Chimeric Antigen Receptor (CAR), both autologous and allogeneic; the most advanced product, CAR-T CD44v6, is waiting to obtain the authorization to start human clinical trials in onco-hematologic indications (AML and MM), following an extensive pre-clinical phase; the product is potentially effective also in several epithelial solid tumors. With regards to allogeneic CARs, MolMed is developing a pipeline based on NK (Natural Killer) cells, following an R&D agreement signed in 2018 with Glycostem. 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, an Orchard 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 field of innovative oncological therapies MolMed pipeline also includes NGR-hTFN, a therapeutical agent for the treatment of solid tumors. 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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