PRESS RELEASE

Presented at ASCO data on the first set of patients from the pivotal Phase III TK008 study: the survival benefit exceeds trial target in acute leukaemia patients

Milan / Chicago, 4 June 2014 – MolMed S.p.A. (MLM.MI) provided at the 50th ASCO annual meeting new data from the ongoing randomised pivotal Phase III study on its cell therapy product TK for high-risk acute leukaemia patients transplanted from partially matched (haplo-identical) donors. The intent-to-treat analysis of the first 24 patients treated with TK indicates a 74% 1-year disease free survival (DFS) as the primary study endpoint: this result largely exceeds the target of 52% DSF for the TK arm vs 30% for the control arm.

Notably, 86% of patients treated with TK were alive at one year (the key secondary study endpoint) and the corresponding figures for patients who achieved immune reconstitution rose to 85% for disease free survival and 100% for overall survival.

The direct impact of TK cells on transplant outcome was confirmed by a very low incidence of relapse (16% - with no relapse in patients receiving higher TK cell doses) and non-relapse mortality (10% - with no deaths observed in patients achieving immune reconstitution).

Claudio Bordignon, Chairman and CEO of MolMed, commented: *"We are particularly proud of the results presented today at the ASCO meeting on the pivotal Phase III trial of the TK cell therapy for acute high risk leukemia patients transplanted from partially matched family donors. When we started this study, our goal was to provide all patients affected by the most aggressive forms of leukemia with the opportunity to undergo bone marrow transplantation, by far their best chance for a permanent cure. For this purpose we developed the TK therapy that allows patients lacking a fully matched donor to access a safer transplantation from partially matched family donors, an approach available to nearly all patients. TK is based on the genetic engineering of the donor immune system that can offer a graft without post-transplant immune-suppression and provide for a rapid and complete reconstitution of the immune system. This therapeutic strategy is characterized by low infection risk, low leukemia relapse rate and, consequently, by a higher probability of cure. Today we report data on the first patients enrolled in this study with an outcome that exceed the target of the trial design. These results strongly support our commitment to complete this large pivotal Phase III study. Moreover, the relevance of the data presented at ASCO is an important validation of our strategic decision to pursue Conditional Marketing Authorization for TK in Europe".*

MolMed has been investing on the TK cell therapy that represents today the largest clinical experience of immuno-gene therapy of tumours worldwide. This extensive program was carried out through the implementation of a centralised manufacturing in a single facility for global distribution. This experience, coupled with the new facilities built by MolMed, represent today an ideal platform for all new technologies of tumour immune-gene therapy based on the different strategies of genetic engineering of the immune system.

The Company would like to thank all patients and their families who placed confidence in this new technology and all the investigators from all transplantation centres who participate the Phase III trial and who contributed to the previous studies.

FROM GENES TO THERAPY

TK008 is coordinated by Dr. Fabio Ciceri, M.D. from the San Raffaele Scientific Institute, principal investigator of the trial who illustrated the results at ASCO and commented: *"Initial results of the Phase III study indicate that in haploidentical transplant recipients TK-cell infusions abate non-relapse mortality and leukemia relapse by providing a fast immune recovery in a dose-dependent manner. HSV-TK suicide gene machinery effectively and timely controlled the graft-vs-host disease (GvHD) in 100% of affected patients with no requirement for long-term immune-suppressive treatment. Results obtained so far appear largely superior to the outcomes reported by large EBMT surveys for the two treatment options of TK008 control arm: T-cell depleted and T-cell replete followed by high-dose cyclophosphamide. These results are of particular relevance in light of the more accessible standard option represented by haploidentical transplants."*

About TK

TK is a cell therapy product, based on the use of genetically engineered donor T cells carrying a "suicide gene". These cells are administered to patients during the haematopoietic stem cell transplantation for the treatment of high risk leukaemia. TK therapy allows to eliminate the post-transplant immunosuppression treatment thus accelerating the immune reconstitution and controlling the immunological consequences arising from the genetic differences with the donor, known as Graft versus Host Disease (GvHD).

In virtue of this approach, HSCT from partially compatible donors is a safer and more effective option, thus potentially increasing the number of candidates for transplantation.

Based on the efficacy and safety data and on the Orphan Drug designation, the Company filed a request for Conditional Marketing Authorisation of TK with the European Medicine Authority in March 2014.

TK008 study

TK008 is a pivotal randomised Phase III trial (TK008) in adult patients affected by high-risk leukaemia undergoing transplant of haematopoietic stem cells collected from partially compatible (haploidentical) family donors. The trial compares the outcome of haplo-transplants with or without TK add-backs, with a 3:1 randomisation ratio in favour of the TK arm.

The primary study end-point is disease-free survival (DFS) - which includes both transplant-related mortality and disease relapse - evaluated on 170 patients. The study is powered to detect an increase in 1-year DFS from 30% in the control arm to 52% in the experimental arm. Secondary end-points include overall survival, reduction of transplant-related mortality, safety and patients' quality of life.

With the aim to provide additional clinical benefit to patients and to significantly increase the potential participation of centres in the trial, the Company implemented in 2012 two important changes in the protocol design of Phase III trial TK008. The first consists in broadening the enrolment criteria to include patients in leukaemic relapse, in addition to those in disease remission; the second change provides for the introduction of a further treatment option in the control arm, based on the use of an unmanipulated transplant followed by cyclophosphamide administration during the post-transplantation period.

About MolMed

MolMed S.p.A. is a biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes two antitumour therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF, a novel vascular targeting agent, in Phase III in malignant pleural mesothelioma and in Phase II in six more indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas. MolMed also offers top-level expertise in cell and gene therapy to third parties to develop, conduct and validate projects from preclinical to Phase III trials, including scale-up and cGMP production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)

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