PRESS RELEASE

TK scientific results and regulatory path will be presented today at the 40° annual meeting of the European Society for Blood and Marrow Transplantation

Milan (Italy), 1 April 2014 – MolMed S.p.A. (MLM.MI) today will present the scientific and regulatory path undertaken with respect to its cell-gene therapy TK at the 40° annual meeting of the European Society for Blood and Marrow Transplantation (EBMT), currently ongoing in Milan.

Based on different academic studies, Phase I-II trials and the currently ongoing pivotal Phase III trial, data obtained on over 130 patients treated with TK cells will be presented. This therapeutic approach has provided patients with high-risk leukemia with: abolition of post transplantation immunosuppression, a rapid immune reconstitution and an effective control of GvHD in the context of haploidentical transplantation. In addition, data on the anti-leukaemia activity of TK cells will be presented for the first time. Overall, these effects led to a relevant increase in survival rates observed in treated patients compared to historical data.

The presentation will interlace the scientific and the regulatory paths starting from the first interactions with the FDA and EMA up to the recent submission of a Conditional Marketing Authorisation.

Claudio Bordignon, Chairman and CEO of MolMed, commented : *"I am particularly grateful to the organizing committee for the opportunity to present our experience in developing a gene therapy approach for bone marrow transplantation in acute leukemias. The results achieved with TK are a clear demonstration of the potential that genetic engineering can provide to the immune system manipulation in the context of bone marrow transplantation. The experience gathered by MolMed in the scientific and regulatory fields can serve as a model for further applications of immune-gene therapy of various malignancies, both hematologic and not"*.

An analysis illustrating data from the first patients treated with TK in the currently ongoing Phase III study (TK008), indicating a further increase in survival rates and an inverse correlation between cell dose administered and the probability of leukemia relapse, will be included in the presentation. Additional data from the TK008 study will be presented at the next congress of the American Society for Clinical Oncology (ASCO), to be held in Chicago from May 30 to June 3.

Two additional presentations are scheduled for today showing the clinical and biological results obtained with the contribution of TK.

Dr. Maria Teresa Lupo-Stanghellini will deliver a speech titled *"T-cell depleted haploidentical stem cell transplantation followed by add-backs of suicide-gene modified donor T-cells offers long term survival free of immune suppression treatment: a 7 years follow-up in 56 patients"*.

Dr. Giacomo Oliveira from the San Raffaele Scientific Institute in Milan will instead give a presentation titled *"Long-term immunological profile and T-cell dynamics in patients treated with allogeneic transplantation and TK-cells for Hematological malignancies"*.

FROM GENES TO THERAPY

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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.

Conditional Marketing Authorisation

The Conditional Marketing Authorisation represents an expedite path for early market authorisation ahead of completion of the pivotal registration studies. Such anticipated authorisation is mainly based on efficacy and safety evidences accumulated in early studies.

A Conditional Marketing Authorisation may be granted only if all the following requirements are met:

1. the risk-benefit balance of the medicinal product is positive;
2. it is likely that the applicant will be in a position to provide the comprehensive clinical data;
3. unmet medical needs will be fulfilled;
4. the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

A Conditional Marketing Authorisation is valid for one year, on a renewable basis. The holder is required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive.

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 design has disease-free survival as the primary end-point - which includes both transplant-related mortality and disease relapse - evaluated on a patient population of 170 patients. The trial will compare the outcome of haplo-transplants with or without TK add-backs, with a 3:1 randomisation ratio in favour of the TK 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.

This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14 May 1999, as subsequently amended.

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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