PRESS RELEASE

MolMed provides an update on the registration strategy for its gene therapy TK in Europe and in the United States

Milan (Italy), 3 February 2014 – MolMed S.p.A. (Milan:MLM) today provided an update on the registration strategy for its gene therapy TK in Europe and in the US.

With regard to the Conditional Approval procedure in EU, after two meetings with the national agencies from rapporteur and co-rapporteur member states designated by the European Medicines Agency (EMA), the Company confirms the expected filing date of the application in the first quarter of 2014.

As far as the Breakthrough Therapy submission is concerned, the U.S. Food and Drug Administration (FDA) has not - at this time - granted the designation for the cell therapy TK as adjunctive treatment in hematopoietic stem cell transplantation (HSCT) for adult patients affected by high risk acute leukaemia. However, the FDA indicates that the Company can submit a new request once new clinical evidence becomes available.

According to this suggestion, MolMed intends to re-apply for Breakthrough Therapy designation in the US since new evidence is now becoming available, including initial efficacy data from the ongoing Phase III clinical trial. These data will be submitted for presentation at next meeting of the American Society of Clinical Oncology (ASCO).

About Breakthrough Therapy

Breakthrough Therapy designation is a new regulatory option available at FDA and is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A breakthrough therapy designation conveys all of the fast track program features as well as more intensive FDA guidance on an efficient drug development program. Details of these regulatory processes can be found at this link:

http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm

The last update provided by the FDA on Dec 31st 2013 shows that only 2 requests have been granted out of the 22 submitted.

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).

About Phase III trial TK008

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TK008 is a pivotal randomised Phase III trial 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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