New data presented at the American Society of Hematology (ASH) confirm the long-term clinical benefit of TK cell therapy on relapse and GvHD after haploidentical transplantation

Milan / San Francisco, December 9, 2014 - MolMed S.p.A. (Milan: MLM) presented new data from three studies on the experimental TK cell therapy in patients with acute leukemia at high risk of relapse who underwent transplantation from a partially compatible donor (haploidentical) at the 56th annual meeting of the *American Society of Hematology (ASH)*). The results showed high survival rates, dose-related anti-leukemic activity and long-term efficiency in the control of GvHD (graft-versus-host disease).

Results presented today at the ASH meeting on a pooled analysis of the Phase II TK007 and Phase III TK008 trials confirmed the potent anti-leukemic effect of the TK cell therapy related to dose with strong statistical significance ($p<0.001$), as evidenced by the absence of leukemia relapse at 4 years after transplantation in those patients who received the highest dose of TK cells.

MolMed's participation at the ASH meeting was completed by a prestigious oral presentation delivered by Dr. Lupo Stanghellini from the Bone Marrow Transplant Unit, San Raffaele Scientific Institute of Milan, who elucidated the TK-driven mechanism by which the suicide gene system is capable of selectively eliminating the donor lymphocytes responsible for GvHD, while sparing the cells able to provide full immune reconstitution, thus providing the patient with prolonged survival without immuno-suppression and free of life-threatening GvHD complications.

Claudio Bordignon, Chairman and CEO of MolMed, comments: "*We are delighted by the new phase III data on the TK cell therapy confirming the high disease-free survival rates, the primary phase III trial endpoint and the scientific basis for the request of Conditional Marketing Authorization from the European regulatory authority. In addition, the long-term analyses have clearly demonstrated the ability of TK cells in inducing a dose-dependent anti-leukemic activity and in fully controlling a hard-to-treat complication such as GvHD.*

I hereby would like to highlight how the innovative value of Italian scientific research and MolMed's contribution are making haploidentical transplants available to patients lacking an identical donor with survival rates comparable to those historically obtained by the best transplant options."

About Phase III trial TK008

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 family donors (haplo-transplant). 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. (Trial identifier on ClinicalTrials.gov: NCT00914628).

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 given after heamatopoietic transplants from healthy donors, and specifically from partially compatible family donors (haplo-transplants), for the treatment of high-risk leukaemia. Add-backs of TK have the potential to allow the retention of immune-protection and anti-leukaemia effects of donor T cells, while promptly controlling and abrogating the possible onset of Graft-versus-Host Disease (GvHD). TK has been granted Orphan Drug designation in both the European Union and the United States.

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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