

## Update on TK clinical benefit presented at ASH and expansion of Phase III trial in Europe

Milan (Italy), 12 December 2011 - MolMed S.p.A. (Milan:MLM) presented at ASH an update on the clinical benefit following treatment with its investigational cell-based therapy TK for high-risk leukaemias in adult patients: patients treated, including the first patients enrolled in the ongoing Phase III trial (TK008), show restoration of a fully functional immune system. MolMed has recently started the international expansion of the trial with recruitment of the first patient in Spain. The trial expects to activate 15 centres in several different European countries, in Israel and in the United States. The primary analysis is expected in 2013.

Claudio Bordignon, MolMed's chairman and CEO, comments: *"These further clinical data confirm that so far patients treated with TK cells benefit from both immune recovery and absence of GvHD morbidity as compared to other available transplant options such as the use of cord blood stem cells. We are now progressing with the international expansion of pivotal Phase III trial in Europe, an important milestone for the clinical development of TK."*

Data presented at the 53<sup>rd</sup> Annual Meeting of the American Society of Hematology (ASH), taking place in San Diego (CA, U.S.), show - in patients treated with TK cells - regeneration and renewed functionality of the thymus, which results into circulation of T cell precursors mediating a robust and specific immune protection. This effect is due to TK cells, which stimulate the production and release of interleukin-7, an important mediator in the development of the immune system: without TK cells engraftment no rise in levels of interleukin-7 is observed and no immune-reconstitution is achieved (ASH poster and abstract #1968). The first author of the abstract, Luca Vago, MD, PhD - in charge of the fundamental studies on immune reconstitution of patients treated with TK - has been granted the important recognition of the ASH Abstract Achievement Award.

### About Phase III trial TK008

TK008 is a pivotal randomised Phase III trial recruiting adult patients affected by high-risk leukaemia undergoing transplant of haematopoietic stem cells derived from the bone marrow of partially compatible donors (haplo-transplant). The trial design, confirmed also following meetings with the U.S. FDA and the EMA, has disease-free survival as 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 add-back strategy. The secondary end-points include overall survival, reduction of transplant-related mortality, safety and patients' quality of life. (Trial identifier on ClinicalTrials.gov: NCT00914628)

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*This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14.5.1999 as subsequently amended.*

### About TK

TK is a cell therapy product, based on the use of genetically engineered donor T cells in association with bone marrow transplants from healthy donors, and particularly from partially compatible family donors (haplo-transplants), for the cure 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 antitumour therapies. In addition to TK, MolMed's pipeline includes another anticancer therapeutic in clinical

development, NGR-hTNF - a novel vascular targeting agent (VTA) - in Phase III in malignant pleural mesothelioma and in Phase II in seven indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, soft tissue sarcomas and mesothelioma as first-line maintenance therapy. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The company's shares are listed on the Milan Stock Exchange, at the Standard segment (class I) of the MTA managed by *Borsa Italiana*.

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