



MolMed announces publication in *Blood* of two articles on the anti-leukaemia properties of the TK therapy

Milan, Italy – June 1st, 2007 – MolMed S.p.A., a biotech company focused on novel anticancer therapies, announced the publication of two back-to-back articles (***Anti-tumor effects of HSV-TK engineered donor lymphocytes after allogeneic stem cell transplantation*** and ***The potential immunogenicity of the TK suicide gene does not prevent full clinical benefit associated with the use of TK-transduced donor lymphocytes in HSCT for haematologic malignancies***), related to the anti-leukaemia properties observed during the clinical development of its TK therapy, in today's issue of the journal *Blood*, introduced by an *Inside Blood* article by an independent editor.

The two articles, both having as corresponding author MolMed's President and CEO Claudio Bordignon, who pioneered the TK technology, give insight into the scientific and clinical background of this cell-based therapeutic approach, first tested in association with transplantation of haematopoietic stem cells (HSCT) from fully compatible donors in the cure of high-risk acute leukaemia. TK therapy is now in clinical development as add-back in HSCT from partially compatible donors, resulting in an unprecedented improvement in survival of patients. In this context, the introduction of TK therapy promotes rapid and sustained immune reconstitution, thus abating transplant-related mortality, as shown by results that will be presented on Sunday, June 3rd, at the Annual Meeting of the American Society of Gene Therapy (ASGT) in Seattle (Wa, USA).

Claudio Bordignon commented: "The treatment with TK proved to be an effective tool for promoting immune reconstitution in both allo- and haplo-HSCT settings: most importantly, it then showed to improve safety and efficacy of haplo-HSCT, thus enabling feasibility of transplantation from partially incompatible family donors, thus making a donor available for all candidate patients lacking a fully compatible one (more than 60%)".

This year, MolMed plans to start a Phase III trial in Europe of TK in the haplo-setting, while a Phase I/II trial will be conducted in the US, managed by the MD Anderson Cancer Center in Houston (Tx, USA).

About acute leukaemia

High-risk acute myeloid leukaemia (AML) is a haematological malignancy for which the best chance of cure is transplantation of haematopoietic stem cells (HSCT) from a healthy family donor. However, feasibility and effectiveness of HSCT are heavily limited by the shortage of fully compatible family donors, which are available only for approximately 30% of the patient population. Partially compatible (haploidentical) donors would be available for nearly all patients, but at present safety and efficacy of this type of transplant is limited by a high rate of transplant-related mortality associated with delayed immune reconstitution.

About TK therapy

TK therapy is based on the use of genetically engineered (TK⁺) donor T lymphocytes, used in association with the haplo-HSC transplant. TK⁺ donor lymphocytes allow to control the main complications associated with haplo-HSCT, while keeping the anti-leukaemia effects of the transplant, thereby increasing both patients' survival and the number of available bone marrow donors.

Orphan drug designation for TK has been granted by the EMEA in 2003, and by the FDA in 2005. MolMed's strategic partner *Takara Bio Inc.* (Japan) is developing TK for the Asian markets.

About MolMed

MolMed S.p.A is a biotechnology company focused on R&D and production of novel anticancer therapies. MolMed has two other anticancer agents, undergoing clinical development for solid tumours: ARENEGYR, a novel VTA, in Phase II in several indications, including colorectal cancer;



M3TK, a therapeutic vaccine for melanoma, in Phase I/II. MolMed's clinical pipeline is supported by a broad portfolio of therapeutic candidates. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy.

For further information, please contact:
Holger Neecke, Business Development Manager

Phone: +39 02 212.77.1
e-mail: info@molmed.com