PRESS RELEASE

Science Translational Medicine *published results of a study highlighting the role of memory stem T cells in the treatment of leukaemia*

The study analysed patients infused with MolMed TK transduced cells

Milan, December 10, 2015 – MolMed S.p.A. (MLM.MI) announces that results of the study titled "Tracking genetically engineered lymphocytes long-term reveals the dynamics of T-cell immunological memory", conducted on patients enrolled in the MolMed's Phase I/II TK007 clinical trial, have been published in "Science Translational Medicine", one of the most influential scientific journals. Researchers and clinicians of IRCCS San Raffaele Hospital in Milan carried out the study and Dr. Giacomo Oliveira, first author of the publication, presented the outcomes during the last American Society of Hematology (ASH) Annual Congress, held in Orlando between the 5th and 8th of December, 2015.

The study investigated immune cells of patients with acute high-risk leukaemia, enrolled in the TK007 clinical trial, who, between 1995 and 2012, underwent haplo-identical hematopoietic stem cell transplantation (haplo-HSCT) and infusion of donor memory T cells, transduced to express the TK suicide gene (Zalmoxis®). Patients' immunologic parameters analysis detected TK cells, characterized them and unravelled the requirements for their long-term persistence.

Ten adult patients were studied, in three the suicide gene TK was activated in order to abrogate the graft versus host disease (GvHD) which set in early after the haplo-HSCT. At a follow-up period in the range of 2 to 14 years, all patients were in complete remission, free of GvHD and with a normal immune system. Furthermore, TK cells were detected in all patients, armed with a still functioning suicide gene.

Analysis of the patients' immune system and of the single engineered TK cells allowed scientists to unravel that memory T cells of "stem" phenotype and having been exposed to the antigen are the most capable to expand and to persist long term.

"Results published in the prestigious Science Translational Medicine *journal,"* commented Professor Claudio Bordignon, President and CEO of MolMed S.p.A. *"represent an important finding and will support the future development of more effective and lasting therapies against leukaemia. Furthermore, long-term efficacy of TK therapy, highlighted once again by this study, confirms the success of the strategy followed thus far by MolMed in developing innovative treatments against cancer. It is exciting to see how progress made in the field of gene and cell therapies, based on genetic engineering of the immune system, opens new scenarios in the treatment of tumours. MolMed, also thanks to Zalmoxis, which allows transplants from partially compatible donors and promotes rapid, broad and long lasting reconstitution of the immune system, is ready to play a significant role in this promising therapeutic area."*

FROM GENES TO THERAPY

MOLMED S.p.A.
Via Olgettina, 58 - 20132 Milan, Italy | Phone +39 02 21277.1 - Fax +39 02 21277.325
info@molmed.com - www.molmed.com
Share capital € 19,841,682.30 fully paid - Office of Milan Company Registry number 1506630 - Tax identification number 11887610159

About Zalmoxis® (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 and is currently investigated as part of the Phase III clinical trials TK008, in adult patients affected by high-risk leukaemia undergoing transplant of haematopoietic stem cells collected from partially compatible family donors (haplo-transplant).

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 medical biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes anti-tumour therapeutics in clinical and preclinical development: Zalmoxis® (TK) is a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, currently in Phase III in high-risk acute leukaemia and under evaluation by EMA for a Conditional Marketing Authorization; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the tumour mass, currently investigated in a broad clinical programme; CAR-CD44v6, an immuno-gene therapy project potentially effective for many haematological malignancies and several epithelial tumours, currently in preclinical development. 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 has its headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and secondary office at OpenZone, in Bresso (Milan). MolMed is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana (ticker Reuters: MLMD.MI).

For further information:

Laura Villa
Investor Relations Director
MolMed S.p.A.
telefono: +39 02 21277.205
fax: +39 02 21277.325
e-mail: investor.relations@molmed.com

Press agent
Federico Ferrari
SEC Relazioni Pubbliche e Istituzionali s.r.l.
phone: +39 02 6249991 – mobile +39 347 6456873
e-mail: ferrari@secrp.it

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