

Results of Phase I/II trial of MolMed's TK therapy in high risk acute leukaemia published in *The Lancet Oncology*

Milan, Italy - April 2 2009 - MolMed S.p.A. (MLM.MI) announces that results obtained in the European multicentric Phase I/II study (TK007) of its TK therapy have been published in the April issue of the prestigious medical journal *The Lancet Oncology*, issued today.

The article - *Infusion of suicide gene-engineered donor lymphocytes after family haploidentical hemopoietic transplantation for leukemia: the TK007 phase I/II trial* - gives insight into the outcome of the trial, conducted on 54 adult patients, that resulted in significant survival improvement of patients affected by high risk acute leukaemia receiving bone marrow transplants from a partially compatible family donor (haplo-transplants). In this context, the introduction of TK therapy allows the use of add-backs of donor T lymphocytes, that promote a rapid and wide immune reconstitution, abating transplant-related mortality and permitting long-term survival.

The intention-to-treat (ITT) analysis shows that treatment with TK proved to greatly improve safety and efficacy of haplo-transplants, thus enabling feasibility and effectiveness of transplants in adult patients from partially incompatible family donors.

Fabio Ciceri and Chiara Bonini, first authors of the article and principal investigators of TK therapy at the San Raffaele Hospital, the coordinator centre of trial TK007, commented: "Treatment with TK proved to be an effective tool for promoting immune reconstitution in transplants from partially compatible donors: most importantly, the remarkable results obtained in this trial definitively show that early and sustained immune-reconstitution results in abatement of mortality, thus making haplo-transplants widely possible in a safe and effective manner".

Claudio Bordignon, Chairman and Chief Executive Officer of MolMed, as well as senior and corresponding author of the article, stressed: "In fact, today TK is the only investigational new therapy addressing the issue of enabling safe and effective haplo-transplants in adult recipients without immune-suppression or immune-depletion, and thereby opening the door of bone marrow transplant to all patients".

The very positive outcome of Phase I/II trial TK007, as already communicated to the market and included in MolMed's Offering Circular, allowed MolMed to get authorisation to begin a Phase III randomised trial that started in Italy in Spring 2008, and will be expanded to other European clinical centres this year: Phase III trial TK008 is pivotal for the registration of TK therapy, that could become among the very first cell therapies using genetically engineered cells to obtain marketing approval.

MolMed's partner for the Asian markets, Takara Bio Inc. (OTCPK:TKBIF), started clinical development of TK in Japan in October 2008, with a Phase I trial in relapsed leukaemia patients conducted at the National Cancer Center in Tokyo.

About TK therapy

TK is a cell-based therapy, based on the use of genetically engineered donor T lymphocytes in association with bone marrow transplants from healthy donors, and particularly from partially compatible family donors (haplo-transplants). Add-backs of such cells allow to keep the immune-protection and anti-leukaemia effects of donor T cells, thereby increasing patients' survival, and making a donor promptly available for all patients lacking a fully compatible donor, that today account for approximately 60% of bone marrow transplant candidates.

Orphan drug designation for TK has been granted in the EU in 2003, and in the US 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 research, development and clinical validation of novel anticancer therapies. In addition to TK, MolMed's pipeline includes another anticancer therapeutic in clinical development: NGR-hTNF, a vascular targeting agent currently in Phase II trials in 5 types of solid tumours: colorectal, liver, small-cell lung and ovarian cancers, and malignant pleural mesothelioma. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The company's shares (MLM.MI) are listed at the Standard segment (class I) of the MTA managed by Borsa Italiana.

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