



MolMed gets regulatory approval to start a Phase III trial in Italy of its TK therapy for high risk acute leukaemia

Milan, Italy – January 22, 2008 – MolMed S.p.A., a biotech company focused on novel anti-tumour therapies, announced that the AIFA, the Italian Health authority, authorised the start in Italy of a Phase III trial (TK008) of MolMed's TK cell therapy in patients affected by high risk acute leukaemias and receiving haematopoietic stem cell transplantation from a partially compatible family donor (haplo-HSCT). AIFA clearance, the very first one in Italy for a Phase III of a cell/gene therapy, requires the completion of analytical characterisation of TK components within the treatment of 20% of patients involved in the study, and follows approval of the clinical protocol, obtained in December 2007 by the Ethical Committee of the first clinical centre involved. In preparing Phase III, MolMed was supported by the EMEA, that provided protocol assistance and scientific advice as granted by the Orphan Drug designation of TK (Orphan Drug is awarded to therapeutics for life-threatening or chronically debilitating conditions affecting not more than 5/10.000 people in the EU). The multicentric, randomised Phase III trial will assess the very positive outcome of Phase I/II trial TK007 that resulted in an exceptional improvement in survival of patients by promoting rapid and sustained immune reconstitution, and proved safety and efficacy of haplo-HSCT, thus enabling feasibility of transplantation from partially incompatible family donors. Claudio Bordignon, President and Chief Executive Officer of MolMed, commented: "The remarkable results obtained in the Phase I/II trial show the importance of TK therapy in making stem cell transplantation available for all candidate patients lacking a fully compatible donor, who are approximately 60% of those who could benefit from this potentially curative treatment". Marco Dieci, Director of Quality & Regulatory Compliance at MolMed, added: "This approval is particularly meaningful also because TK is one of the very few cell/gene therapies in Phase III all over the world, and thus could be among the very first ones to obtain marketing approval".

This year, MolMed also plans to start a Phase I/II trial of TK in the US, managed by the MD Anderson Cancer Center in Houston (Texas).

About acute leukaemia

High-risk acute leukaemia is a haematological malignancy for which the only potentially curative treatment is transplantation of haematopoietic stem cells (HSCT) from a healthy donor. However, feasibility and effectiveness of HSCT are heavily limited by the shortage of fully compatible donors, which are available only for approximately 30-40% of the patient population. Partially compatible (haploidentical) family 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 haplo-HSCT. 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 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 clinical validation of novel anticancer therapies. MolMed has two other anti-tumour therapeutics in clinical development: ARENEGYR, a novel vascular targeting agent (VTA), in Phase II in four indications; M3TK, a therapeutic vaccine, in Phase I/II in advanced melanoma. 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.

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