PRESS RELEASE

TK submission for Conditional Approval validated by EMA

Milan (Italy), 26 March 2014 – MolMed S.p.A. (Milan:MLM) announces that the European Medicines Agency (EMA) has validated the submission of the Conditional Marketing Authorisation for TK, a novel proprietary investigational cell-gene therapy. The data review of the submitted dossier starts today.

TK is an adjunctive treatment in hematopoietic stem cell transplantation for patients affected by high risk leukaemia. TK has been granted orphan drug status by the European Commission.

MolMed is also glad to announce that the Company has been invited by the European Society for Blood and Marrow Transplantation (EMBT) to illustrate the scientific and regulatory path of TK which – with more than 120 patients treated so far - is the largest cell-gene therapy application ever performed. Claudio Bordignon, CEO and president of the Board, will give a presentation on the topic next Tuesday 1st of April during the plenary session of the 40th annual meeting of the EMBT, which will be held in Milan from March 30th to April 2nd.

Conditional Marketing Authorisation

The Conditional Marketing Authorisation represents an expedite path for early market authorisation ahead of completion of the pivotal registration studies. Such anticipated authorisation is mainly based on efficacy and safety evidences accumulated in early studies.

A Conditional Marketing Authorisation may be granted only if all the following requirements are met:

1. the risk-benefit balance of the medicinal product is positive;
2. it is likely that the applicant will be in a position to provide the comprehensive clinical data;
3. unmet medical needs will be fulfilled;
4. the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

A Conditional Marketing Authorisation is valid for one year, on a renewable basis. The holder is required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive.

About TK

TK is a cell therapy product, based on the use of genetically engineered donor T cells carrying a “suicide gene”. These cells are administered to patients during the haematopoietic stem cell transplantation for the treatment of high risk leukaemia. TK therapy allows to eliminate the post-transplant immunosuppression treatment thus accelerating the immune reconstitution and controlling the immunological consequences arising from the genetic differences with the donor, known as Graft versus Host Disease (GvHD).

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 € 10,485,541.89 fully paid - Office of Milan Company Registry number 1506630 - Tax identification number 11887610159

In virtue of this approach, HSCT from partially compatible donors is a safer and more effective option, thus potentially increasing the number of candidates for transplantation.

TK008 study

TK008 is a pivotal randomised Phase III trial (TK008) in adult patients affected by high-risk leukaemia undergoing transplant of haematopoietic stem cells collected from partially compatible (haploidentical) family donors.

The trial design has disease-free survival as the 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 arm. Secondary end-points include overall survival, reduction of transplant-related mortality, safety and patients' quality of life.

With the aim to provide additional clinical benefit to patients and to significantly increase the potential participation of centres in the trial, the Company implemented in 2012 two important changes in the protocol design of Phase III trial TK008. The first consists in broadening the enrolment criteria to include patients in leukaemic relapse, in addition to those in disease remission; the second change provides for the introduction of a further treatment option in the control arm, based on the use of an unmanipulated transplant followed by cyclophosphamide administration during the post-transplantation period.

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 biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes two antitumour therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF, a novel vascular targeting agent, in Phase III in malignant pleural mesothelioma and in Phase II in six more indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas. 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 is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)

For further information:

Marina Del Bue
General Manager Business & Administration
Investor Relations Director *ad int.*
MolMed S.p.A.
phone: +39 02 21277.371
fax: +39 02 21277.325

e-mail: investor.relations@molmed.com

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

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