Press release

MolMed's partner Takara Bio Inc. starts a Phase I trial of TK for relapsed leukaemia in Japan

Milan (Italy), October 7, 2008 – MolMed S.p.A. (Milan:MLM) announces that its strategic partner for the Asian markets, the Japanese public biotech company Takara Bio Inc. (OTCPK:TKBIF), has entered into an agreement with the National Cancer Center of Japan to start a Phase I clinical trial of MolMed's TK cell-based therapy for the treatment of patients with relapsed leukaemia having undergone haematopoietic stem cell transplant (HSCT) from a fully compatible donor. The agreement follows the regulatory approval of the trial by the Japanese Pharmaceuticals and Medical Devices Agency.

The objective of the trial, to be conducted at the National Cancer Center Hospital in Tokyo, is to assess the safety of TK-expressing donor T-cells and the control of graft-versus-host disease (GvHD) in relapsed leukaemia patients having received HSCT from a fully compatible donor (allo-HSCT). This is the first clinical trial of an *ex vivo* gene therapy to be conducted in Japan, and it is expected to be an important toehold for the development of cell and gene therapy in the country.

TK is being developed worldwide under an alliance between MolMed and Takara Bio Inc., in which Japanese and selected Asian rights to TK for haematological malignancies are out-licensed to Takara Bio. As part of the alliance, MolMed has also in-licensed European and US rights to Takara Bio's RetroNectin®, a crucial reagent in clinical-grade, retrovirus-mediated gene therapy techniques which is used in the donor T-cell transduction process with the TK gene. The partnership includes sharing of data on the clinical development of TK.

In spring 2008, MolMed started a Phase III multicentric, randomised trial of TK in high-risk leukaemia patients undergoing HSCT from partially incompatible donors (haplo-HSCT). This trial, started in Italy and expected to be extended to other European clinical centres, will seek confirmation of the very positive outcome of a European Phase I/II trial in the same indication, conducted on more than 50 patients, that resulted in an exceptional improvement in survival by promoting rapid and sustained immune reconstitution. By proving the safety and efficacy of haplo-HSCT, the trial demonstrated the feasibility of transplantation from partially incompatible family donors while maintaining the clinical benefits of donor T-cells.

Orphan drug designation for TK has been granted in Europe since 2003, and in the US since 2005.

About TK therapy

TK therapy allows leukaemia patients to receive haematopoietic stem cell transplants (HSCT) from healthy donors, either fully or partially compatible, retaining the protective effects of donor T-cells while controlling the risk of graft-versus-host disease (GvHD) - a major cause of mortality in HSCT due to an aggression of donor T-cells to the recipient's organs and tissues. TK therapy allows to overcome the issue of GvHD by administering donor T-cells which have previously been modified to carry a selective conditional elimination system, based on the introduction of the TK gene: this gene encodes the enzyme thymidine-kinase from the herpes simplex virus (HSV-TK), and makes the T-cells sensitive to the antiviral drug ganciclovir. These modified donor T-cells promote immune reconstitution, and are very likely to exert an anti-leukaemia effect against residual cancer cells: in the event that GvHD occurrs, the T-cells responsible for the aggression can be selectively destroyed by administration of ganciclovir.

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 two other novel therapeutics in clinical development: NGR-hTNF, a vascular targeting agent, in Phase II trials in four different indications (colorectal, liver and small-cell lung cancer, and mesothelioma); M3TK, a therapeutic vaccine in Phase I/II trial in advanced melanoma. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. MolMed is a public company listed on the Milan Stock Exchange (Milan: MLM), on the Standard segment (class I) of the MTA managed by Borsa Italiana.

phone +39 02 21277.1
fax +39 02 21277 220
e-mail: info@molmed.com
web: http://www.molmed.com

MolMed S.p.A.
Via Olgettina 58
20132 Milan (Italy)
VAT nr. & fiscal code 11887610159

About Takara Bio Inc.

Takara Bio Inc. is a biotechnology company based in Shiga, Japan. Takara Bio was the first company to market PCR technology in Japan, and is also the developer of the RetroNectin® reagent, a worldwide standard in gene therapy protocols. Takara Bio Inc. is a provider of reagents and equipment to the life science research market and has research and product development activities in the field of gene and cell-based therapy, as well as in agricultural biotechnology. Through strategic alliances with other industry leaders, the company aims to extend its reach around the world. Takara Bio Inc. is a public company listed on the Tokyo Stock Exchange (OTCPK:TKBIF).

For further information, please contact:

Holger Neecke
Director Business Development
Investor Relations
MolMed S.p.A.
phone: +39 02 21277.205
fax: +39 02 21277.325
e-mail: investor.relations@molmed.com

Elena Lungagnani
Communication Manager
MolMed S.p.A.
phone: +39 02 21277.207
fax: +39 02 21277.325
e-mail: media.relations@molmed.com

Takara Bio Inc.
Corporate Communications
e-mail: bio-ir@takara-bio.co.jp