PRESS RELEASE

MolMed receives positive COMP opinion on the orphan drug designation for Zalmoxis®

- *Zalmoxis clinical benefit confirmed*
- *Market exclusivity rights granted*

Milan (Italy), July 1, 2016 – Following the positive opinion on the Conditional Market Authorisation issued on June 24 by the CHMP, in conjunction with the CAT (Committee for Advanced Therapies), the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA), just confirmed the orphan drug designation for Zalmoxis, the first patient-specific immunogene therapy, as adjunctive treatment in haplo-identical haematopoietic stem-cell transplantation (haplo-HSCT) for adult patients with high-risk haematological malignancies.

The orphan drug designation is granted to drugs intended to diagnose, prevent or treat life-threatening or very serious conditions that are too uncommon to make their development convenient according to normal market conditions, and whose clinical benefit is clearly recognized. In fact, Zalmoxis improves overall survival, reduces non-relapse mortality, and cuts the incidence of chronic graft-versus-host disease in patients undergoing haplo-HSCT. To encourage the development of these medicines, a specific Regulation in the EU grants a ten years market exclusivity rights for the specific indication, once the drug is approved.

Riccardo Palmisano, CEO of MolMed S.p.A., commented: "*This new positive opinion coming from COMP is highly significant and very important for MolMed. It confirms the clinical benefit of Zalmoxis in addressing a significant unmet clinical need for such a life-threatening condition, thus coupling with the CHMP positive opinion issued last Friday. Furthermore, the orphan drug designation represents a huge competitive advantage because it grants 10 years of market exclusivity, thus allowing us to set Zalmoxis as the leading therapy available on the market in treating adult patients with high-risk haematological malignancies, undergoing haplo-indentical HSCT.*"

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 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 prophylaxis, currently in Phase III in high-risk acute leukaemia and granted a positive opinion by EMA's CHMP for a Conditional Marketing Authorisation; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the cancer and to the concentration of immune system cells into the tumour mass, currently investigated in a broad clinical programme, involving more than 1000 treated patients; 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 a local unit 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 & Communication 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

DISCLAIMER