

MolMed provides update on Zafiride Conditional Marketing Authorization application

Milan, June 1, 2017 – Following recent interactions with the European Medicine Agency (EMA), MolMed S.p.A. today announced its decision to withdraw the Conditional Marketing Authorisation (CMA) application submitted to the European Medicines Agency (EMA) in December 2016 for Zafiride (NGR-hTNF), its investigational anticancer drug, for the treatment of adult patients with advanced malignant pleural mesothelioma who progressed within six months after the first-line pemetrexed-based therapy.

MolMed, in fact, following the clarification meeting held with Rapporteurs and EMA Representative regarding the concerns raised in the original day 120 List of Questions, concluded not to have sufficient time to complete, within the timeframe assigned by CHMP for this procedure, the activities aimed to obtain the data regarding the product manufacturing and control.

MolMed believes that Zafiride is a valuable anti-cancer therapy and reserves the right to make further submissions at a future date in this or other therapeutic indications. For this reason, the Company will keep on scouting potential partners for both clinical and industrial development of the product.

This press release is written in compliance with public disclosure obligations established by Consob's (Italian securities & exchange commission) Issuers Regulation.

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 € 20,312,682.30 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 Conditional Marketing Authorisation by the European Commission; 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 is an immune 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 manufacturing of viral vectors and patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and an operating unit at OpenZone in Bresso (Milan, Italy). 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.

phone: +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@segrp.it

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