PRESS RELEASE

The European Medicines Agency has validated the submission of Conditional Marketing Authorisation for NGR-hTNF

Milan (Italy), December 23, 2016 – MolMed S.p.A. (Milan:MLM) announces that the European Medicines Agency (EMA) has validated the submission of the Conditional Marketing Authorisation (CMA) application for NGR-hTNF as treatment of adult patients with malignant pleural mesothelioma progressing within six months after the first-line pemetrexed-based therapy. Review of the submitted dossier therefore starts today.

About Conditional Marketing Authorisation

Conditional Marketing Authorisation represents an expedite path for early market authorisation ahead of completion of pivotal registration trials. 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 NGR-hTNF

NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to tumour blood vessels and concentration of immune system cells into the tumour mass. NGR-hTNF has been investigated in a broad and comprehensive clinical programme involving more than 1000 patients, Phase III trial NGR015 in malignant pleural mesothelioma as second line-treatment and Phase II trial NGR019 in malignant pleural mesothelioma as first-line maintenance therapy. Other indications investigated in completed Phase II trials include colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas.

NGR-hTNF has been granted Orphan Drug designation for the treatment of mesothelioma in both the European Union and the US. In addition, it has been granted the same designation also for the treatment of liver cancer.

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.

FROM GENES TO THERAPY

MOLMED S.p.A.

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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).

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