

## *MolMed files a Conditional Marketing Authorisation in the European Union for NGR-hTNF*

Milan (Italy), December 6, 2016 – MolMed S.p.A. (Milan:MLM) announces that the Company has filed a Conditional Marketing Authorisation (CMA) application with the European Medicines Agency (EMA) for NGR-hTNF, its investigational anticancer drug, for the following indication: treatment of adult patients with advanced malignant pleural mesothelioma who progressed within six months after the first-line pemetrexed-based therapy.

In fact, MolMed believes that NGR-hTNF fulfils the following requirements for eligibility for a CMA, according to the principle of EMA/509951/2006: (i) the indication is a life-threatening or seriously debilitating disease; (ii) NGR-hTNF has been granted Orphan Drug Designation by the European Commission for the treatment of mesothelioma.

The clinical dossier supporting the CMA application is based mainly on a completed randomised Phase III trial NGR015, investigating NGR-hTNF as second-line treatment, either alone or in combination with a chemotherapy.

The trial results showed clinical benefit with NGR-hTNF in the predefined patient subgroup – representing 50% of the treated trial population - with short treatment-free interval (TFI), i.e. patients rapidly progressing after the end of the first-line chemotherapy; precisely in this patient population, affected by a particularly aggressive disease with very severe prognosis, the treatment produced a 100% increase of 1-year overall survival; in addition, NGR-hTNF showed a high safety level in the whole population treated. The complete trial data are included in an oral presentation held at ASCO 2015, available at the link here below:

[http://www.molmed.com/sites/default/files/uploads/publications/2688/ngr015\\_asco\\_2015\\_abs\\_7501\\_oral.pdf](http://www.molmed.com/sites/default/files/uploads/publications/2688/ngr015_asco_2015_abs_7501_oral.pdf)

Riccardo Palmisano, MolMed's CEO, commented: *“By filing this Conditional Marketing Authorisation application, we have achieved a new and important milestone in the clinical development of NGR-hTNF. We believe that the significant survival improvement observed in those patients who suffer from a particularly aggressive and resistant form of mesothelioma with no viable therapeutic options to date, confirms the potential of NGR-hTNF's clinical use and, more importantly, can offer a new safe and effective treatment option for patients affected by such a severe cancer disease.”*

### FROM GENES TO THERAPY

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**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 the US as well; in addition, it has been granted Orphan Drug designation for the treatment of liver cancer in both the EU and the US.

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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 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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