

MolMed reports top line results of NGR-hTNF in the phase III trial in malignant pleural mesothelioma

Milan (Italy), 5 May 2014 – MolMed S.p.A. (MLM.MI) today announced the results of the double-blinded, placebo-controlled Phase III trial of NGR-hTNF versus best investigator choice in 400 patients with malignant pleural mesothelioma who had previously failed a first-line chemotherapy.

Despite not meeting its primary endpoint of improving overall survival (OS) in the entire population, the study showed a statistically significant (unstratified $p=0.02$; stratified $p=0.01$) 40% improvement of OS in patients with poorer prognosis who had progressed during or shortly after first-line chemotherapy. These patients represent 50% of the entire patient population and were identified by a pre-specified analysis based on prior treatment-free interval.

This clinical parameter will allow to easily identifying patients who derive most clinical benefit from NGR-hTNF in combination with the chemotherapy of choice.

Consistent with the overall survival improvement in this patient population, a 40% percent longer progression-free survival (PFS) was also reported for the NGR-hTNF treated arm in those patients who presented a more aggressive, chemo-resistant disease.

In addition to the efficacy data, NGR-hTNF confirmed in this large patient population its very favourable tolerability profile also in combination with the three chemotherapeutic agents administered in this study (gemcitabine, vinorelbine and doxorubicin).

NGR-hTNF has already been granted Orphan Drug designation for the treatment of mesothelioma in both the EU and the US.

Claudio Bordignon, Chairman and CEO of MolMed, commented: *“The results obtained in a pre-specified population of high-risk patients represent an important reward for the Company’s mission and effort in improving survival and quality of life of cancer patients, even if the primary endpoint was not reached in the entire population. For the first time in malignant pleural mesothelioma a highly significant clinical benefit was achieved in a large subpopulation with the worst prognosis, represented by patients refractory or rapidly progressing after first line treatment. In addition, these data provide confirmation of NGR-hTNF effect on survival already observed in Phase II studies in other indications. Pending a more in depth evaluation, these top line results already provide potential to pursue conditional marketing authorisation and further clinical development in mesothelioma and other indications.”*

For the same pathology the Company is running a randomised Phase II study on NGR-hTNF as maintenance therapy after completion of first line chemotherapy (NGR019). The study aims at extending the treatment-free interval of those patients who did not progress after first line, providing them with a long term therapy with a high tolerability profile.

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 € 10,874,215.42 fully paid - Office of Milan Company Registry number 1506630 - Tax identification number 11887610159

About NGR-hTNF

NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the tumour mass. NGR-hTNF is being investigated in a large clinical program, including a Phase III trial in malignant pleural mesothelioma (second line), a Phase II trial in malignant pleural mesothelioma (first-line maintenance therapy) and five Phase II trials in colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas.

In particular, completed randomised clinical trials showed statistically significant increase in overall survival in squamous cell NSCLC and soft tissue sarcomas. Recent results from the Phase III study in malignant pleural mesothelioma confirmed the ability of NGR-hTNF in treating particularly challenging cancer indications.

Updated results from MolMed clinical development program will be presented at most relevant forthcoming meetings, including the ASCO 2014 in June.

NGR-hTNF has been granted Orphan Drug designation for the treatment of mesothelioma and liver cancer in both the EU and the US.

About Phase III trial NGR015

NGR015 is a pivotal randomised, double-blind, placebo-controlled, international, multicentre Phase III trial performed on 400 malignant pleural mesothelioma patients (enrolled in 48 centres in the EU, US, Canada and Egypt) whose disease progressed after a pemetrexed-based chemotherapy. The trial is powered to detect a survival benefit for NGR-hTNF, when combined with best investigator's choice (BIC), where BIC includes either best supportive care alone or in combination with chemotherapy (either doxorubicin, or gemcitabine, or vinorelbine). NGR-hTNF is administered according to the dose and schedule that were confirmed as the most efficacious in Phase II trials: 0.8 µg/m² weekly, until disease progression.

About Phase III trial NGR019

NGR019 is a randomised, double-blind, placebo-controlled, international, multicentre Phase II trial on 100 adult pleural mesothelioma patients with non-progressive disease after a pemetrexed-based chemotherapy. The trial is powered to detect a progression-free survival benefit for NGR-hTNF, when combined with best supportive care (BSC). NGR-hTNF is administered according to the dose and schedule that were confirmed as the most efficacious in Phase II trials: 0.8 µg/m² weekly, until disease progression. Secondary endpoints include overall survival, tumour response, safety and quality of life.

Conditional Marketing Authorisation

The Conditional Marketing Authorisation represents an expedite path for early market authorisation ahead of completion Phase III clinical development. 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 allows the Company to commercialise the product in advance and 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 pleural mesothelioma

Pleural mesothelioma is a form of cancer strongly related with repeated exposure to asbestos fibres (for more information please refer to Park et al, Global Magnitude of Reported and Unreported Mesothelioma, Environmental Health Perspectives, 2011). Pleural mesothelioma is a tumor that develops in the tissue that lines the chest cavity.

With an incidence of approximately 1/100,000, pleural mesothelioma is still a relatively rare type of cancer, but has been progressing quickly in the past 20 years as incidence rates have continuously increased. Pleural mesothelioma has a long latency period and symptoms are non-specific, so that in most cases diagnosis is difficult before the advanced stage of the disease is reached. Research indicates that pleural mesothelioma may affect each year more than 10,000 people in the EU and the US. Currently, only one therapy has been approved for first-line treatment, whilst the elevated need for first-line maintenance and second line treatment remains unmet. Clinical development of NGR-hTNF is aimed at filling this therapeutic gap.

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 biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes two antitumour therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF, a novel vascular targeting agent, in Phase III in malignant pleural mesothelioma and in Phase II in six more indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas. 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 is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)



For further information:

Marina Del Bue

**General Manager Business & Administration
Investor Relations Director *ad int.***

MolMed S.p.A.

phone: +39 02 21277.371

fax: +39 02 21277.325

e-mail: investor.relations@molmed.com

Press agent

Federico Ferrari

SEC Relazioni Pubbliche e Istituzionali srl

phone: +39 02 6249991 – mobile +39 347 6456873

e-mail: ferrari@secrp.it

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