

Results of Phase II trial of NGR-hTNF in mesothelioma published by the *Journal of Clinical Oncology*

Milan (Italy), 21 April 2010 - MolMed S.p.A. (Milan:MLM) announces that the positive results of a Phase II trial of its investigational anticancer drug NGR-hTNF in malignant pleural mesothelioma have been published by the *Journal of Clinical Oncology* (*JCO 10.1200/JCO.2009.27.3649*; early release published online ahead of print on April 20, 2010). Also on the basis of these results, NGR-hTNF has been granted Orphan Drug designation for the treatment of malignant mesothelioma, in both the EU and the US. MolMed has just started a pivotal Phase III trial for this indication.

The article - *Phase II Study of Asparagine-Glycine-Arginine-Human Tumor Necrosis Factor α , a selective Vascular Targeting Agent, in previously treated patients with malignant pleural mesothelioma* - gives insight into the outcome of a single-arm, open-label, multicentre Phase II trial (NGR010), where NGR-hTNF was administered as monotherapy - either every three weeks or every week - in 57 chemo-pretreated patients. The results, anticipated at the most important international meetings, show an overall disease control rate of 46% with a median duration of 4.7 months. A clear advantage of the weekly intensification of the treatment is highlighted in terms of disease control duration (9.1 vs 4.4 months). In a recent analysis, the clinical benefit resulted into a prolongation of overall survival, which is doubled in patients achieving initial disease control.

Claudio Bordignon, MolMed's chairman and CEO, comments: "The fact that the results of the Phase II trial have been selected for publication in the most prestigious medical journal in clinical oncology further endorses what we see as an important step forward in the development of a novel treatment option for mesothelioma, a disease with a very high unmet medical need. Our commitment in this field is now represented by the pivotal Phase III trial which is underway and foresees the enrolment of 400 patients".

About MolMed's Phase III trial (NGR015) in mesothelioma

NGR015 is a pivotal randomised, double-blind, placebo-controlled, international multicentre Phase III trial, expecting to enrol 400 adult patients affected by malignant pleural mesothelioma with disease progressing after chemotherapy. The main endpoint of the trial is overall survival; secondary endpoints include progression-free survival, disease control rate, safety, and patient quality of life.

About malignant pleural mesothelioma (MPM)

MPM is a form of cancer that is almost always caused by repeated exposition to asbestos fibers. With an incidence of approximately 1/100,000, MPM is still a relatively rare type of cancer, but has been progressing fast in the past 20 years as incidence rates have continuously increased. MPM has a long latency period of the disease, and symptoms are non-specific, so that in most cases diagnosis is difficult before the advanced stage of the disease is reached. Treatment of malignant mesothelioma using conventional therapies has not proven to be successful, leaving affected patients with a poor prognosis and limited survival time. (www.euorphan.com)

About NGR-hTNF

NGR-hTNF is a vascular targeting agent with unique mode of action, and a first-in-class compound in the class of peptide/cytokine complexes able to selectively target the tumour vasculature. It consists of a tumour homing peptide (NGR) that selectively binds tumour blood vessels, fused to the human cytokine TNF. NGR-hTNF is undergoing clinical development both as monotherapy and in combination therapy, in a total of six indications. In addition to mesothelioma, NGR-hTNF has been tested as monotherapy in Phase II trials in liver and colorectal cancer. Phase II trials in combination therapy include: with Xelox for colorectal cancer; with doxorubicin for small-cell lung cancer, and for ovarian

cancer; with cisplatin-based regimens in a randomised trial for non-small cell lung cancer, *versus* chemotherapy alone. MolMed is also conducting a Phase I trial aimed at the exploration of safety and preliminary anticancer activity of NGR-hTNF at high doses. In addition to mesothelioma, NGR-hTNF has been granted Orphan Drug designation - in both the EU and the US - also for the treatment of liver cancer. NGR-hTNF has been discovered by researchers at the San Raffaele Scientific Institute and licensed by MolMed.

About MolMed

MolMed S.p.A is a biotechnology company focused on research, development and clinical validation of novel antitumour therapies. In addition to NGR-hTNF, MolMed's pipeline includes another anticancer therapeutic in clinical development, TK, a cell-based therapy enabling bone marrow transplant from partially compatible donors, in Phase III for high-risk acute leukaemias. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The company's shares (MLM) are listed at the Standard segment (class I) of the MTA managed by Borsa Italiana.

This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14.5.1999 as subsequently amended.

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