

## MolMed receives FDA clearance of IND to initiate a Phase III trial of NGR-hTNF in mesothelioma in the United States

Milan (Italy), 24 May 2010 - MolMed S.p.A. announces that it received clearance from the U.S. Food and Drug Administration (FDA) for the IND filed to initiate a Phase III clinical trial of its investigational antitumour drug NGR-hTNF for the treatment of malignant pleural mesothelioma (NGR015) in the United States. The trial is currently recruiting patients in Italy, and MolMed also plans to involve other clinical centres in the European Union.

Claudio Bordignon, MolMed's chairman and CEO, comments: "We are very pleased with the FDA's clearance of our IND, as it allows MolMed to carry out next steps related to the first Phase III trial of NGR-hTNF in the United States. We have now achieved a further corporate milestone in the development of NGR-hTNF, which may represent a novel treatment option for malignant mesothelioma, an orphan disease with high unmet medical need."

### About Phase III trial NGR015 for the treatment of malignant pleural mesothelioma

NGR015 is a pivotal randomised, double-blind, placebo-controlled, international multicentre Phase III trial, expecting to enrol 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. (Clinicaltrials.gov trial identifier: NCT01098266).

### Results of Phase II trial of NGR-hTNF in mesothelioma

In a completed Phase II trial (NGR010), a single-arm, open-label, multicentre trial, NGR-hTNF was administered as monotherapy - either every three weeks or every week - in 57 chemo-pretreated patients. The results, presented in 2009 at ASCO and ECCO-ESMO and published in the last issue of the *Journal of Clinical Oncology* (Vol. 28, Nr. 15, May 20, 2010), showed an overall disease control rate of 46% with a median duration of 4.7 months. The comparison of progression-free time between the weekly and the tri-weekly cohort showed a clear advantage of the treatment intensification approach (9.1 vs 4.4 months): accordingly, the weekly schedule was chosen in designing Phase III trial NGR015.

In 2008, NGR-hTNF has been granted Orphan Drug designation for the treatment of malignant mesothelioma in both the EU and the US.

### About malignant pleural mesothelioma (MPM)

MPM is a form of cancer that is almost always caused by repeated exposure to asbestos fibers. With an incidence of approximately 1/100,000, MPM is still a relatively rare type of cancer, but incidence rates have increased rapidly in the past 20 years. The disease 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. Treatment of malignant mesothelioma using conventional therapies has not proven to be successful, leaving affected patients with a poor prognosis and limited life expectancy.

### 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. Ongoing Phase II trials in combination

therapy include: with Xelox for colorectal cancer, with doxorubicin for small-cell lung cancer and for ovarian cancer, and 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.

### 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.

*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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