Press release

MolMed starts Phase III trial of NGR-hTNF in mesothelioma

Milan (Italy), 13 April 2010 – MolMed S.p.A. (Milan:MLM) announces the treatment of the first patient in a pivotal Phase III trial (NGR015) of its investigational antitumour drug NGR-hTNF in malignant pleural mesothelioma, a condition linked with repeated exposition to asbestos fibers.

Claudio Bordignon, MolMed's chairman and CEO, comments: "We are really proud of this important milestone, as NGR-hTNF may represent a novel treatment option for malignant mesothelioma, a disease with very high unmet medical need. Based on the positive results of a multicentre Phase II trial, this Phase III trial is optimally designed to investigate the full therapeutic potential of NGR-hTNF in the treatment of mesothelioma."

About Phase III trial NGR015

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 a pemetrexed-based chemotherapy. The trial investigates the administration of NGR-hTNF plus best investigator's choice (BIC) versus placebo plus BIC, where BIC includes either supportive care alone or combined with one chemotherapeutic agent (either doxorubicin, or gemcitabine, or vinorelbine). Randomisation ratio will be 1:1. Before randomisation, investigators decide for each patient if he/she is candidate to either supportive care alone or combined with chemotherapy; patients are then randomly assigned to either of the two treatment arms by specific stratification factors.

NGR-hTNF is given intravenously as 1-hour infusion at 0.8 $\mu g/m^2$ once a week, until disease progression; placebo follows the same administration schedule in the control arm. BIC is delivered, where applicable and as appropriate, according to Institutional and literature guidelines, and chemotherapy is administered as per standard clinical practice. The primary endpoint of the trial is overall survival. Secondary endpoints include progression-free survival, disease control rate, safety, and patient quality of life.

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, 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.

Also on the basis of Phase II results, 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 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.

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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.

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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