

## Update of five clinical trials of NGR-hTNF, MolMed's anticancer investigational biologic drug, presented at ECCO-ESMO 2009

Milan (Italy), September 24, 2009 - MolMed S.p.A. (Milan:MLM) presented updates of five clinical trials of its vascular targeting agent NGR-hTNF at the joint Annual Meeting of the European Cancer Organisation and of the European Society of Medical Oncology (ECCO-ESMO), that took place in Berlin on September 20-23, 2009: one of the five trials, Phase II trial NGR010 in malignant pleural mesothelioma, was selected for oral presentation. New data presented include top-line results for NGR008, a Phase II trial in pre-treated patients with primary liver cancer, and first results for NGR005, a Phase II trial in combination with Xelox in heavily pre-treated patients affected by advanced colorectal cancer. Finally, the clinical development update on NGR-hTNF presented at ECCO-ESMO also includes long-term follow-up data of two other clinical trials of NGR-hTNF: Phase II trial NGR006, testing NGR-hTNF as monotherapy in colorectal cancer, and Phase I trial NGR004, testing NGR-hTNF in combination with cisplatin.

Claudio Bordignon, chairman and CEO of MolMed, comments: "We are particularly pleased that the Scientific Committee of ECCO-ESMO chose our study in mesothelioma for oral presentation within the proffered paper session devoted to advanced trials in lung cancers, thus recognising the high quality of its results and the value of our effort in the development of a new anticancer agent. Altogether, the overall picture offered by the results of the five trials presented at the ECCO-ESMO meeting confirms the opportunity of further clinical development of NGR-hTNF, either as monotherapy or in combination with standard chemotherapy, in several indications. These include both high-incidence tumours, and less frequent diseases with highly unmet medical need.

- NGR010 - Phase II trial as monotherapy in malignant pleural mesothelioma, selected for oral presentation (ECCO-ESMO abstract 9011): in this trial, NGR-hTNF was administered as monotherapy in 57 chemo-pretreated patients, either every three weeks (43 patients) or every week (14 patients). Results show a disease control rate of 46% with a median duration of 4.7 months, and a median overall survival of over one year (12.1 months). Moreover, the comparison of progression-free survival between the tri-weekly and the weekly cohort shows clear advantage of the dose intensification approach. Accordingly, MolMed will use the weekly schedule in further clinical development of NGR-hTNF for the treatment of mesothelioma.
- NGR008 - Phase II trial as monotherapy in primary liver carcinoma (ECCO-ESMO abstract 6617): in this trial, NGR-hTNF was tested in 40 previously treated patients, that received NGR-hTNF either every three weeks (27 patients) or every week (13 patients). Updated results show a disease control rate of 30% maintained for a median of 4.3 months, a median overall survival of nearly nine (8.9) months, and 1-year and 2-year survival rates of 27% and 17%, respectively, after a median follow-up of two years. A case of complete eradication of the tumour is ongoing since May 2008, and a case of partial regression of the tumour lesion lasting for 4.4 months was observed.
- NGR005 - Phase I trial in combination with Xelox (ECCO-ESMO abstract 6066) for colorectal cancer: the trial involved 24 patients failing standard treatment regimens - including oxaliplatin-based regimens - treated with a combination of a fixed dose of Xelox (capecitabine + oxaliplatin) with either of two different doses of NGR-hTNF: 12 patients received the low dose of NGR-hTNF used in all other Phase II trials ( $0.8 \mu\text{g}/\text{m}^2$ ), while 12 patients received a high dose ( $45 \mu\text{g}/\text{m}^2$ ). First results show that both combinations are well tolerated, with no apparent worsening of chemo-associated toxicity. In the cohort treated with low-dose NGR-hTNF, disease control rate was of 50%, including one case of partial response, with a median duration of 5.0 months. In the cohort treated with high-dose NGR-hTNF, disease control rate was of 33%, with a median duration of 3.3 months.
- NGR006 - Phase II trial as monotherapy in heavily pre-treated colorectal cancer patients (ECCO-ESMO abstract 6062): update of this trial, involving 46 patients and reaching a median overall survival of over one year (13.1 months), consisted of long-term follow up data.

- NGR004 - Phase I trial in combination with cisplatin (ECCO-ESMO abstract 1228): in this trial, involving 22 patients with with different types of solid tumours refractory to available therapeutic options - 12 of which previously treated with a platinum-based regimen - results show that the combination is extremely well tolerated, and that it induced a disease control rate of 36%, including several disease stabilisations achieved by platinum pre-treated patients. On the basis of the positive outcome of this trial, MolMed started in June 2009 a randomised Phase II trial (NGR014) in combination of either of two cisplatin-based regimens - cisplatin/gemcitabine or cisplatin/pemetrexed - *versus* the two chemotherapeutic regimens alone, as first line treatment in non-small cell lung cancer.

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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 in a tumour homing peptide (NGR) that selectively binds tumour blood vessels, fused to the powerful human anticancer cytokine TNF. NGR-hTNF is undergoing clinical development both as single agent and in combination with several different chemotherapeutic agents. Indications investigated in Phase II trials as single agent include colorectal cancer, hepatocellular carcinoma and malignant pleural mesothelioma. 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 (cis/gem or cis/pem) in a randomised trial in non-small cell lung cancer. MolMed also started a Phase I trial aimed at the exploration of safety and preliminary anticancer activity of NGR-hTNF at high doses. In 2008, NGR-hTNF was granted Orphan Drug designation for malignant mesothelioma both in the EU and in the US.

#### **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.

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