

**Clinical update of NGR-hTNF presented at ASCO 2009:  
Top-line results of Phase II trial in mesothelioma  
Combination with cisplatin entering Phase II in lung cancer**

**Long-term data of Phase II trial in colorectal cancer - Interim update of Phase II trial in liver cancer**

Milan (Italy), June 1, 2009 - MolMed S.p.A. (Milan:MLM) presented updates of 4 clinical trials of its vascular targeting agent NGR-hTNF at the 45<sup>th</sup> ASCO Annual Meeting, including positive top-line results for NGR010, a Phase II trial as monotherapy in chemo-pretreated patients with malignant pleural mesothelioma (MPM), and for NGR004, a Phase I trial of NGR-hTNF in combination with cisplatin.

- **NGR010 - Phase II trial in malignant pleural mesothelioma (ASCO abstract 7582):** in this multicentre, single-arm trial, NGR-hTNF was tested as second line therapy in 57 chemo-pretreated patients treated with a low dose of NGR-hTNF given intravenously, either every 3 weeks (43 patients) or every week (14 patients). Analysis of study results shows a disease control rate of 46% maintained for a median of 4.7 months, and a median overall survival of over one year, while median survival rates historically reported in this setting are of approximately 8-9 months. Moreover, analysis of progression-free survival in the tri-weekly and weekly cohorts shows a strong advantage of the dose intensification approach: median progression-free survival at 6 months in the weekly cohort was three-fold higher than in the tri-weekly cohort (36% vs 13%), and the median duration of disease control was more than doubled in the weekly cohort (9.1 vs 4.4. months).
- **NGR004 - Phase I trial in combination with cisplatin (ASCO abstract 3570):** in this trial involving 22 patients with refractory solid tumours, 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 disease stabilisations achieved by platinum pre-treated patients.

Claudio Bordignon, chairman and CEO of MolMed, comments: "We are really very happy with these results. Indeed, the positive outcome of the Phase II trial in mesothelioma warrants pursuing evaluation of the weekly schedule of NGR-hTNF in a randomised Phase III trial. As to the combination of NGR-hTNF with cisplatin, the favourable safety profile and the very interesting clinical activity in heavily pre-treated patients assessed in the Phase I trial, leads us to investigate this combination therapy as first line treatment in a randomised Phase II trial for lung cancer, a platinum-sensitive tumour: the protocol has already been approved, and patient recruitment will start soon".

New data presented at ASCO also concern two more Phase II clinical trials of NGR-hTNF:

- follow-up data of NGR006, a trial in 46 heavily pre-treated colorectal cancer patients (ASCO abstract 4088), showing a median survival time more than doubled with respect to best supportive care data, and with 35% of patients still alive after a follow-up of almost two years;
- updated interim results of NGR008, a trial in 39 patients affected by hepatocellular carcinoma (ASCO abstract 15500), where median overall survival has not yet been reached after 8 months, and a case of complete tumour eradication is ongoing for more than one year.

#### About NGR-hTNF

NGR-hTNF (ARENEGYR) 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: currently, in addition to Phase II trials as single agent in colorectal cancer, hepatocellular carcinoma and mesothelioma, and to Phase I trial in combination with cisplatin, it is also tested in Phase II combination trials, with Xelox for colorectal cancer, and with doxorubicin for small-cell lung cancer and for ovarian 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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