

MolMed's vascular targeting agent NGR-hTNF for solid tumours selected for oral presentation at ANGIO 2009

Milan (Italy), February 6, 2009 - MolMed S.p.A. (Milan:MLM) announces that data showing the mechanism of action and clinical development outcomes of NGR-hTNF, its investigational anticancer drug targeting tumour blood vessels, were selected for an oral presentation at ANGIO 2009, the 11th International Symposium on Anti-Angiogenic Agents. The meeting, taking place in San Diego (USA) on February 5-7, 2009, features recent advances and future directions in basic and clinical cancer research.

The presentation, held on February 5 by MolMed's chairman and CEO Claudio Bordignon, gave an insight on the mechanism of action of NGR-hTNF, which is a direct-acting vascular targeting agent consisting of the human cytokine TNF coupled to NGR, a tumour homing peptide. NGR targets a particular form of CD13, a receptor selectively expressed by endothelial cells of human tumour vessels during the formation of new blood vessels, while it does not home to tumour-unrelated human tissues. The data presented show that the binding of NGR-hTNF to tumour endothelial cells induces cell death by eliciting defined signalling pathways through the surface receptors for both moieties of the molecule, i.e. CD13 and TNF-R, resulting into prevention of tumour growth.

The update on the clinical development programme of NGR-hTNF focused mainly on a summary of three Phase II trials in patients with advanced colorectal cancer (CRC), hepatocellular carcinoma (HCC), and malignant pleural mesothelioma (MPM), treated with a low dose of NGR-hTNF given intravenously every 3 weeks, presented at the ESMO Meeting and at the ASCO-GI Symposium:

- in CRC: a median overall survival of 13.1 months, versus 6 months reported in literature for best supportive care (BSC);
- in HCC: dramatic tumour shrinkages in this highly hypervascularised tumour, including one patient achieving a complete necrosis after 4 cycles of NGR-hTNF, now lasting for more than 8 months;
- in MPM: nearly doubled progression-free survival and an improved overall survival (median not yet reached, and projected to be more than 1 year) with respect to literature data for BSC, along with a case of clear evidence of tumour regression.

In addition, in these 3 trials further cohorts of patients were enrolled, treated with the same dose of NGR-hTNF, but administered once a week instead of every 3 weeks. Claudio Bordignon comments: "We are pleased and encouraged by the initial evidence of an advantage of a dose intensification approach, with a weekly administration schedule, emerging in mesothelioma patients".

Top line results of these Phase II studies are expected by the end of May. In 2008, the first results of the Phase II trial in mesothelioma allowed NGR-hTNF to obtain Orphan Drug designation for this indication both in the EU and in the US. A Phase II trial of NGR-hTNF in combination with doxorubicin for a new indication, ovarian cancer, started in December 2008.

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 of a tumour homing peptide (NGR) selectively binding 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, it is also tested in Phase II combination trials, with Xelox for colorectal cancer, and with doxorubicin for small-cell lung cancer. 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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