

NGR-hTNF (ARENEGYR): new and updated efficacy data of Phase II trials in three different types of solid tumours presented at ESMO 2008

Milan (Italy), September 16, 2008 - MolMed S.p.A. (Milan:MLM) presented new and updated efficacy and safety data of three single-arm Phase II clinical trials of NGR-hTNF (ARENEGYR), conducted in patients with advanced colorectal cancer (CRC), hepatocellular carcinoma (HCC), and malignant pleural mesothelioma (MPM), at the 33rd European Society of Medical Oncology (ESMO) Meeting in Stockholm. After obtaining several evidences of partial responses in different indications, for the first time a complete response was observed with NGR-hTNF in a hepatocellular carcinoma patient.

The primary endpoint of these three trials is progression free survival. The data were presented in poster sessions, and demonstrated a well-tolerated toxicity profile in pre-treated and poor-prognosis patient populations. All patients received low dose NGR-hTNF intravenous infusion every 3 weeks, with tumour reassessment performed every 6 weeks. NGR-hTNF antitumour activity resulted in the following clinical benefits:

- **Phase II trial NGR006 in colorectal cancer (ESMO abstract 397P):** updated efficacy analysis conducted on 32 patients (on a total of 46 enrolled in the study) and presented on September 14th, showed that NGR-hTNF doubled survival times compared to best supportive care data (BSC) reported in literature in this heavily pre-treated patient population, with a median overall survival of 13.1 months *versus* 6 months reported for BSC.
- **Phase II trial NGR008 in hepatocellular carcinoma (ESMO abstract 546P):** in the first 27 patients enrolled in the study, interim data presented on September 14th showed dramatic tumour shrinkages in this highly hypervascularised tumour, including a complete necrosis after 4 cycles of NGR-hTNF, evaluated by contrast-enhanced CT scan.
- **Phase II trial NGR010 in malignant pleural mesothelioma (ESMO abstract 334P):** updated preliminary analysis conducted on 41 patients (on a total of 57 enrolled in the study) and presented on September 15th, showed a nearly doubled progression-free survival and an improved overall survival (median not yet reached, and projected to be more than 12 months) with respect to best supportive care data reported in literature, along with a case of clear evidence of tumour regression.

MolMed also presented first data of a Phase I trial of NGR-hTNF in combination with cisplatin, a largely used chemotherapeutic agent, particularly in the treatment of lung cancer (ESMO abstract 483P, displayed as poster on September 13th). The data showed that the combination of NGR-hTNF with cisplatin is safe, along with evidence of clinical activity in terms of disease stabilisations and partial responses, also in patients pre-treated with cisplatin.

Claudio Bordignon, Chairman and Chief Executive Officer of MolMed, commented: "These very positive data on antitumour activity of NGR-hTNF in considerably different tumour types, together with further confirmation of its favourable safety profile, provide clear evidence of the therapeutic potential of our candidate drug, and strongly support its full clinical development in all these indications."

Complete data of the studies in colorectal cancer and in mesothelioma will become available by October and by December 2008, respectively, while the trial in hepatocellular carcinoma will be completed by early 2009. The first results in mesothelioma allowed NGR-hTNF to obtain Orphan Drug designation for this indication both in the EU and in the US.

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. The resulting molecule has unique biological properties, including induction of tumour vascular permeability and normalisation, and a direct biological antitumour activity. 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 has been granted Orphan Drug designation for malignant mesothelioma both in the EU and in the US.

About colorectal cancer (CRC)

CRC, also called colon cancer or large bowel cancer, includes tumour growths in the colon, rectum and appendix. It is the third most common form of cancer worldwide, with approximately 1 million new cases diagnosed every year, and the second leading cause of cancer-related death in the Western world, with a yearly mortality of 655,000 people worldwide. Many colorectal cancers are thought to arise from adenomatous polyps in the colon: these mushroom-like growths are usually benign, but some may develop into cancer over time. Therapy is usually through surgery, which in many cases is followed by chemotherapy. While the current use of chemotherapy and novel monoclonal antibody-based therapies have increased the median survival rate, most patients with advanced colorectal cancer develop resistance or become refractory to these therapies over time: therefore, there is an urgent need for new treatment options.

About hepatocellular carcinoma (HCC)

HCC is a primary cancer of the liver. Most cases of HCC are secondary to either a viral hepatitis infection (hepatitis B or C) or cirrhosis. In countries where hepatitis is not endemic, most malignant cancers in the liver are not primary HCC, but metastases from a different primary tumour site, e.g. the colon. Treatment options of HCC and prognosis are dependent on many factors, but especially on tumor size and staging. Tumour grade is also important. High-grade tumors will have a poor prognosis, while low-grade tumors may go unnoticed for many years. The usual outcome is poor, because only 10 to 20% of hepatocellular carcinomas can be removed completely using surgery, and if the cancer cannot be completely removed the disease is usually deadly within 3 to 6 months.

About malignant pleural mesothelioma (MPM)

MPM is a type of cancer mostly caused by previous exposure to asbestos. In this cancer, malignant cells develop in the pleura (the protective lining that covers the lungs and chest cavity). With an incidence of approximately 1/100,000, MPM is still a relatively rare cancer, but has been progressing fast in the past 20 years as incidence rates have continuously increased, and are forecasted to accelerate dramatically in the next years, largely due to the progressive degradation of buildings containing asbestos. Symptoms may not appear until many years after exposure to asbestos: because of this long latency, and because most common symptoms, such as cough and chest pain, are common to many other diseases conditions, early diagnosis is often difficult and patients may not be diagnosed until the disease is at advanced stage. Treatment of malignant mesothelioma using conventional therapies has not proven to be successful, and patients have a median survival time of 6-12 months after disease presentation.

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 two more novel therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplant from partially compatible donors, in Phase III in high-risk acute leukaemias; and M3TK, a therapeutic vaccine, in Phase I/II in advanced melanoma. 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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