

The US Food and Drug Administration grants Orphan Drug designation of NGR-hTNF for treatment of liver cancer

Milan (Italy), 12 October 2009 - MolMed S.p.A. (Milan:MLM) announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation of MolMed's investigational new antitumour drug NGR-hTNF for treatment of liver cancer (reference code #05-20044).

"Orphan Drug designation of NGR-hTNF for liver cancer treatment represents an important acknowledgement by the FDA of our efforts in the development of a new anticancer agent, and of the preliminary results in the treatment of this very poor-prognosis disease, obtained in a still ongoing Phase II trial", comments Claudio Bordignon, MolMed's chairman and CEO.

Updated results of the trial (NGR008), involving 40 patients, were recently presented at the ECCO-ESMO Congress 2009. Top-line study results include a median survival time of 8.9 months. The 1-year and 2-year survival rates were 27% and 17%, respectively. Disease control was achieved in 30% of patients, with a median duration of 4.3 months. A complete tumour eradication is still ongoing since May 2008, and an additional partial tumour regression lasting for 4.4 months was observed.

About Orphan Drug designation

Orphan Drug designation is granted to therapeutics intended for treatment of life-threatening or chronically debilitating pathologies affecting no more than 5 in 10,000 people. The orphan medicinal products designated to date cover a wide variety of rare diseases, for which there are either no or few satisfactory treatment options. The Orphan Drug designation confers several benefits to drug development and, upon drug authorisation, marketing exclusivity for a period of 7 years in the U.S.

About liver cancer

Liver cancer, or hepatocellular carcinoma, is a primary tumour of the liver. In most cases, it is secondary to either a viral infection (hepatitis B or C) or cirrhosis. In countries where hepatitis is not endemic, most malignant cancers in the liver are not primary liver cancers but metastases (spread) of cancer from a different primary tumour site, e.g. the colon. Treatment options of liver cancer and prognosis are dependent on many factors, but especially on tumour stage. 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 10-20% of hepatocellular carcinomas can be removed completely using surgery. If the cancer cannot be completely removed, the untreated disease in advanced stage is usually associated to a median survival time of about 6 months.

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 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, besides liver cancer, colorectal cancer 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 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 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.

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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