

The European Commission grants Orphan Drug designation for MolMed's vascular targeting agent ARENEGYR in the treatment of mesothelioma

Milan (Italy), 6 June 2008 - MolMed S.p.A. (Milan:MLM) announces that the European Commission has granted Orphan Drug designation for MolMed's investigational new antitumour therapeutic drug ARENEGYR (NGR-hTNF α) in the treatment of malignant pleural mesothelioma (MPM). The Commission decision, dated June 3rd 2008, follows the positive opinion released on April 9 by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA). ARENEGYR is now listed in the Community Register of orphan medicinal products for human use with number EU/3/08/549.

Malignant pleural mesothelioma (MPM) is a form of cancer that is almost always caused by repeated exposition to asbestos fibers. With an incidence of approximately 1/100,000, MPM is still a relatively rare type of cancer, but has been progressing fast in the past 20 years as incidence rates have continuously increased. MPM has a long latency period of the disease, and symptoms are non-specific, so that in most cases diagnosis is difficult before the advanced stage of the disease is reached. 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.

"Orphan Drug designation for ARENEGYR in mesothelioma represents a fundamental acknowledgement of the interesting early efficacy and safety results achieved in an ongoing Phase II trial, with 53 patients recruited so far, and which we just presented at the ASCO Annual meeting 2008", says Claudio Bordignon, MolMed's president and CEO. "The analysis of preliminary study results presented at ASCO, conducted on 41 patients, already gave evidence of substantial clinical benefits in terms of long-lasting disease control and promising survivals in chemo-pretreated mesothelioma patients. In particular, it shows improved overall survival, and nearly doubled progression-free survival with respect to best supportive care data reported in literature. The consolidated results as to survival data will be available by early December, and I am convinced they will open the way to the full clinical development of ARENEGYR in this setting".

About Orphan Drug designation

European 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 only unsatisfactory treatment options. The Orphan Drug designation confers several benefits to drug development, including the possibility to reduce time to reach the market, protocol assistance and scientific advice provided by the EMA throughout the drug development process, reduced fees for filing drug approval and, upon authorisation, and marketing exclusivity for a period of 10 years.

About ARENEGYR

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. ARENEGYR consists of a tumour homing peptide (NGR) selectively binding tumour blood vessels, fused to the powerful anticancer cytokine hTNF α . The resulting molecule has unique biological properties, including induction of tumour vascular permeability and normalisation, and a direct biological antitumour activity. ARENEGYR is undergoing clinical development both as single agent and in combination with several different chemotherapeutic agents: currently, in addition to mesothelioma and colorectal cancer, single agent Phase II trials are ongoing in hepatocellular carcinoma and small-cell lung cancer, and ARENEGYR for colorectal cancer is also being tested in a Phase II trial in combination with Xelox. Also ongoing is a Phase I trial in combination with cisplatin, while a Phase I trial in combination with doxorubicin was successfully completed.

About MolMed

MolMed S.p.A is a biotechnology company focused on research, development and clinical validation of novel antitumour therapies. In addition to ARENEGYR, 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's clinical pipeline is supported by a broad portfolio of therapeutic candidates. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The company's shares (MLM) are listed at the MTA managed by Borsa Italiana (Standard segment, class I).

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