

Publication of Phase II trial results of NGR-hTNF in liver cancer by the *British Journal of Cancer*

Milan (Italy), August 31, 2010 - MolMed S.p.A. (Milan:MLM) announces that the positive results of a phase II trial of its investigational anticancer drug NGR-hTNF in liver cancer have been published by the *British Journal of Cancer* (doi:10.1038/sj.bjc.6605858; published online, ahead of print).

The article - "*Activity and safety of NGR-hTNF, a selective vascular-targeting agent, in previously treated patients with advanced hepatocellular carcinoma*" - gives insight into the outcome of a single-arm, open-label, multicentre Phase II trial (NGR008), where NGR-hTNF was tested as monotherapy in 40 pretreated patients affected by advanced-stage hepatocellular carcinoma (HCC) resistant to either locoregional, systemic treatments or both. The article describes a clear single-agent antitumour activity of NGR-hTNF.

The overall results, already presented at the most important international meetings, show a disease control rate of 30% for a median time of 4.3 months and a median overall survival of nearly nine (8.9) months, compared to a median survival of about six months if untreated. Importantly, a patient previously refractory to the only targeted drug registered in HCC, sorafenib, achieved a complete durable tumour eradication ongoing for more than 2 years, and a previously untreated patient with impaired liver function achieved a partial response of 78%. The confirmed response rate of 7% registered in this study is encouraging and compares favourably with response rates reported in phase II trials using molecularly targeted therapies and in phase III trials using sorafenib in the same indication. Moreover, NGR-hTNF was extremely well tolerated, without high grade treatment-related toxicities noted in this hard-to-treat patient population due to common underlying cirrhosis.

Claudio Bordignon, MolMed's chairman and CEO, comments: "The two observed tumour regressions in such highly vascularised tumours provide clinical evidence of the antivascular mode of action of NGR-hTNF. Altogether, such relevant single-agent antitumour activity, the very favourable toxicity profile and the efficacy maintained also in patients with liver dysfunction or prior treatment strongly suggest that NGR-hTNF deserves further development in advanced-stage HCC, both as single agent or in combination in a randomised study design. This indication represents a very high unmet medical need, especially for sorafenib-resistant patients for whom no drugs are currently approved."

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 human cytokine TNF. NGR-hTNF is undergoing clinical development both as monotherapy and in combination therapy, in a total of six indications. Currently, randomised trials of NGR-hTNF include a Phase III trial for malignant pleural mesothelioma and a Phase II trial for non-small-cell lung cancer. Additional Phase II trials of NGR-hTNF include completed trials for liver cancer, for colorectal cancer and for small-cell lung cancer, and an ongoing trial for ovarian cancer. NGR-hTNF has been granted Orphan Drug designation - in both the EU and the US - for the treatment of mesothelioma and of liver cancer. NGR-hTNF has been discovered by researchers at the San Raffaele Scientific Institute and licensed by MolMed.

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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