

New data presented at ASCO on NGR-hTNF show significantly extended survival in very poor-prognosis mesothelioma and sarcoma patient populations

Milan / Chicago, 3 June 2014 – A statistically significant 40% improvement of both overall survival and progression-free survival in a large population of patients, identified by a pre-specified analysis on the prior treatment-free interval, and who presented a very dismal prognosis was reported by MolMed S.p.A. (MLM.MI) this weekend, at the 50th ASCO annual meeting.

These efficacy results were observed in an international randomized Phase III study evaluating the investigational drug NGR-hTNF in combination with best investigator choice in 400 patients with malignant pleural mesothelioma (MPM) who had previously failed a first-line chemotherapy.

The magnitude of treatment effect increased with NGR-hTNF duration and was particularly marked in patients receiving at least three months of therapy, with a median survival time nearly doubled in patients treated with NGR-hTNF compared to control patients: 16.5 vs 9.8 months, respectively.

Claudio Bordignon, Chairman and CEO of MolMed, commented: *“The results presented at ASCO on the efficacy of NGR-hTNF in the treatment of the patient affected by the more aggressive form of malignant pleural mesothelioma confirm, in a large Phase III trial, the therapeutic potential of this molecule already observed in Phase II in chemo-resistant squamous NSCL carcinoma, soft-tissue sarcoma, and ovarian carcinoma. Having been able to extend the median survival time to more than 16 months in patients treated for at least 12 weeks is a success for the study and, more important, offers the perspective of a relevant clinical benefit to patients affected by the more aggressive form of mesothelioma. These results represent for MolMed the basis to aggressively pursue the next crucial steps for the future of this molecule: the definition of the best and fastest registration path, and the identification of a suitable partner for offering to NGR-hTNF the possibility to express its full potential as an anti-cancer agent of broad application.”*

The data reported at ASCO, mainly obtained in combination with either gemcitabine or vinorelbine in a very aggressive and chemo-resistant disease, assume particular relevance as they are confirmatory of the efficacy previously shown by NGR-hTNF plus gemcitabine in the first-line Phase II study in squamous lung cancer patients.

Furthermore, NGR-hTNF confirmed in this large patient population its very favourable tolerability profile in combination with the three different chemotherapeutic agents administered in this study (gemcitabine, vinorelbine and doxorubicin).

An additional two randomized Phase II studies reported at ASCO meeting clearly established the effect of NGR-hTNF on survival.

In the four-arm randomized Phase II study in sarcoma patients, the low-dose weekly NGR-hTNF plus doxorubicin regimen induced a statistically significant doubled survival time, as compared with the other schedules given at high dose in combination with doxorubicin or as monotherapy at low or high dose. The 3-year survival rate with this schedule exceeded 40% and, notably, similar results were reported for both

FROM GENES TO THERAPY

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chemo-naïve and pretreated patients, thus confirming the elevated NGR-hTNF efficacy in more aggressive, chemo-resistant disease.

In the randomized Phase II study in resistant / refractory ovarian cancer patients, NGR-hTNF in combination with an anthracycline improved overall survival in patients with normal or high baseline lymphocyte counts, as compared to patients receiving an anthracycline alone.

Taken together, these clinical evidence is also consistent with the drug mechanism of action, that also promotes an increased intratumoral chemotherapy uptake and interaction with the patient immune system.

About NGR-hTNF

NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the tumour mass. NGR-hTNF is being investigated in a large clinical program, including a Phase III trial in malignant pleural mesothelioma (second line), a Phase II trial in malignant pleural mesothelioma (first-line maintenance therapy) and five Phase II trials in colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas.

NGR-hTNF has been granted Orphan Drug designation for the treatment of mesothelioma and liver cancer in both the EU and the US.

This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14 May 1999, as subsequently amended.

About MolMed

MolMed S.p.A. is a biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes two antitumour therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF, a novel vascular targeting agent, in Phase III in malignant pleural mesothelioma and in Phase II in six more indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas. MolMed also offers top-level expertise in cell and gene therapy to third parties to develop, conduct and validate projects from preclinical to Phase III trials, including scale-up and cGMP production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)

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