

Oral presentation at ASCO 2015 of survival data in poor prognosis patients achieved in the Phase III trial on NGR-hTNF treatment in pleural mesothelioma

Milan (Italy), 1 June 2015 – MolMed S.p.A. (MLM.MI) announces that the complete results of the Phase III trial with its investigational therapeutic NGR-hTNF in mesothelioma were presented and discussed orally in the "Lung Cancer-NSCLC local-regional/SCLC/Other Thoracic Cancers" session at the 51st ASCO Annual Meeting underway in Chicago (IL, USA) from May 29th to June 2nd.

The international phase III trial, which started in 2010 and whose top line results were released in 2014, showed a statistically significant 45% improvement in overall survival in patients who progressed more rapidly after first-line treatment. This outcome was observed in the 50% of patients with a poorer prognosis, while the primary endpoint was not met for the entire population.

In this poor prognosis patient population, the robustness of the benefit induced by NGR-hTNF in combination with chemotherapy, over chemotherapy alone, has been confirmed by the efficacy consistently reported across all patient subgroups, defined on the basis of well-established risk factors (e.g. histology, performance status, age, sex, etc.), and across all the other study endpoints, with NGR-hTNF able to prolong progression-free survival time by 45%, to reduce early progression rate by 45% and to increase the survival duration in patients with disease control by 65%.

The meaningfulness of results achieved in mesothelioma patients has been further endorsed by additional analyses related to the phase III trial data that were also presented at the ASCO conference in two poster presentations.

The first analysis highlighted the value of the clinical parameter - the treatment-free interval after first-line therapy - in easily identifying patients who benefited most from NGR-hTNF treatment and in defining the increased aggressiveness and poor prognosis of disease. The second analysis indicated the rationale underlying the increased NGR-hTNF effects observed in the patient population presenting with disease characterized by an augmented tumor angiogenesis (as assessed by high circulating lactate dehydrogenase levels), and the key role of patient immune status in predicting NGR-hTNF efficacy. Indeed, in those patients who presented with elevated blood markers of angiogenesis and of the immune response, overall survival improved by 72% and progression-free survival by 89% with NGR-hTNF plus chemotherapy compared with chemotherapy alone.

These clinical results are also in line with the drug's hypothesized mechanism of action, which is based on an improved intratumoral penetration of chemotherapeutic agents and increased tumor lymphocyte infiltration, thanks to NGR-hTNF's activity on newly formed tumor vasculature.

MolMed's global effort in the treatment of mesothelioma is further reinforced by the currently ongoing randomized Phase II trial with NGR-hTNF given as a maintenance approach after completion of first-line therapy.

Claudio Bordignon, Chairman and CEO of MolMed, commented: "The oral presentation of the data

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discussed at the ASCO meeting acknowledges the value of the results achieved by NGR-hTNF in those patients who suffer from a resistant disease and are most in need of treatment options, and significantly confirms the therapeutic potential of the molecule already observed in other tumor indications evaluated in Phase II trials. The identification of patients who benefit most from NGR-hTNF, their extended survival time, and the consistently reported efficacy represent three key results of the study and, more importantly, offer the perspective of a relevant and appropriate treatment choice for patients with poorer prognosis".

These results represent the basis for the Company to pursue the next steps, including initiation of the registration process, and the further clinical development of NGR-hTNF.

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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