

Highly promising preclinical data in leukaemia and solid tumours for CAR-CD44v6 presented at the 58th Annual Meeting of the American Society of Hematology

Milan (Italy), December 5, 2016 – MolMed S.p.A. announces that first exciting results from preclinical studies conducted on its proprietary cancer immune-gene therapy project CAR-CD44v6 have been presented today at the 58th Annual Meeting of the American Society of Hematology (ASH), held in San Diego (USA) from December 3 to December 6, 2016. Dr Attilio Bondanza, Head of Innovative Immunotherapies Unit, Division of Immunology, Transplantation and Infectious Diseases, at San Raffaele Hospital Scientific Institute, showed these results during an oral presentation titled “Monocytes Are Required for Both Optimal Anti-Leukemic Efficacy and the Cytokine Release Syndrome By CAR-T Cells: Lessons from an Innovative Xenotolerant Mouse Model”

The CAR-CD44v6 is part of the CAR-T (Chimeric antigen-receptor-engineered T cells) family: lymphocytes armed with chimeric receptors that have demonstrated high anti-tumour potential, also against tumours - above all haematological - which are particularly aggressive and resistant to traditional therapies. Strong potential in curing chronic and acute leukaemia refractory to standard treatments has been demonstrated for CAR-T cells.

The CAR-CD44v6, which has already been successfully tested in appropriate murine models, represents a product candidate with a particularly high therapeutic potential, as it specifically recognises variant 6 (v6) of the antigen CD44 (CD44v6), expressed by many haematological malignancies, including acute myeloid leukaemia and multiple myeloma - as well as by several epithelial tumours, including breast, colon, pancreatic, head-and-neck and lung carcinomas.

Outcomes presented today are from an innovative xenotolerant mouse model of CAR-T cell immunotherapy, for studying the determinants of CAR-T cell efficacy and associated toxicities, and from a human lung adenocarcinoma model. Results on T cells *ex vivo* transduced with MolMed's CD44v6 CAR-T highlighted very promising features confirming its efficacy and safety profile, and sustaining its therapeutic potential in solid tumours.

On the subject of leukaemia, preclinical outcomes confirmed CD44v6 CAR-T efficacy and showed higher safety profile compared to CD19 CAR-T cells; but even more noteworthy are outcomes on solid tumours, as results from a human lung adenocarcinoma model showed interesting and highly promising features of MolMed's CD44v6 CAR-T project. In particular, T cells expressing the CD44v6 CAR-T very efficiently and preferentially migrate to the tumour site, where they exert impressive tumour killing potential. Indeed, the analysis performed shortly after the treatment showed that, in the tumour lesions, neoplastic cells were almost entirely eliminated and replaced by CAR-T cells.

Riccardo Palmisano, MolMed's CEO, said: “*We are very proud and excited for the outcomes presented today: they confirm the wisdom and foresight of the choice we made in the recent past, when we acquired CD44v6 CAR-T project from San Raffaele Hospital to enter in the highly dynamic and promising field of immune-gene*

FROM GENES TO THERAPY

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therapy of cancer. Today's presentation stressed the features that can differentiate our product versus other CAR-T projects currently under development: CAR-CD44v6 has demonstrated, in preclinical studies, to be efficient and potentially safer in leukaemia and, even more importantly, to be efficient in human lung adenocarcinoma, one of the "big killers" among solid tumours. Encouraged by and based on these preliminary results, supporting the feasibility of a future exploitation of the CD44v6 CAR-T in the therapy of solid tumours too, we will be able to properly outline the potential of the project, its place in therapy, and finally to better define the development path to follow to initiate trials in man".

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 medical biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes anti-tumour therapeutics in clinical and preclinical development: Zalmoxis® (TK) is a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression prophylaxis, currently in Phase III in high-risk acute leukaemia and granted a Conditional Marketing Authorisation by the European Commission; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the cancer and to the concentration of immune system cells into the tumour mass, currently investigated in a broad clinical programme, involving more than 1000 treated patients; CAR-CD44v6, an immune gene therapy project potentially effective for many haematological malignancies and several epithelial tumours, currently in preclinical development. 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 Biotechnology Department (DIBIT) in Milan, Italy, and a local unit at OpenZone, in Bresso (Milan). MolMed is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana (ticker Reuters: MLMD.MI).

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