

New relevant safety data of CD44v6 CAR-T cells will be presented at the 4th International Congress on Stem Cell Transplantation and Cellular Therapies

Milan (Italy), October 25th, 2017 – MolMed S.p.A. announces that new relevant pre-clinical *in vivo* safety data on its proprietary cancer immunogene therapy project CAR-CD44v6, will be presented on the 27th of October during a workshop titled “Approaches to potentially overcome CAR-T cell toxicity: anticytokine antibodies and suicides genes” by Dr. Attilio Bondanza, Head of Innovative Immunotherapies Unit, Division of Immunology, Transplantation and Infectious Diseases, at San Raffaele Hospital Scientific Institute, at the 4th International Congress on Stem Cell Transplantation and Cellular Therapies – COSTEM - (Berlin, October 26-29, 2017).

The seminar aims to provide suitable methods able to overcome CAR-T cell toxicity and thus potentially exploit this breakthrough technology efficacy in treating leukemia as well as solid tumours. In fact, adoptive immunotherapy based on T cells genetically modified with a tumour-reactive chimeric antigen receptor (CAR) is an innovative therapeutic concept, promising to eradicate cancer without causing secondary chronic diseases. However, CAR-T cells also have the potential to elicit life-threatening toxicities including cytokine release syndrome, neurologic toxicity and potential on-target/off-tumour toxicity. Therefore, managing CAR-T cells and abrogating their potential toxicity has become a critical step in the successful application of this emerging technology and for its clinical development.

MolMed’s CAR-T cells target the CD44 isoform v6 (CD44v6) which is expressed on haematological malignant cells, as well as in some epithelial tumours and not on non-malignant cells, with the exception of monocytes and keratinocytes, where the expression is very weak. This immunogene therapy project has already demonstrated high preclinical *in vitro* and *in vivo* efficacy against leukaemia, but above all shown promising therapeutic potential in solid tumours expressing CD44v6 and higher safety profile compared to other projects in development.

Outcomes that will be presented at COSTEM represent a major progress respect to the data shared at the 22nd EHA Annual Congress (June 25th, 2017), and during the 58th ASH Annual Meeting (December 6th, 2016).

Dr. Bondanza will show the latest results generated in his lab in a full-thickness human skin xenograft mouse model. In this model, differently from CAR-T cells targeting the epidermal growth factor receptor (EGFR),

FROM GENES TO THERAPY

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CD44v6 CAR-T cells do not cause skin toxicity, as demonstrated by reduced accumulation of engineered cells in the derma and at the dermo-epidermal junction. The results obtained in this model establish a crucial in vivo proof-of concept of the safety of CD44v6 CAR-T cells towards tissues, as the skin, that express even minimal levels of this antigen.

Professor Claudio Bordignon, MolMed's Chairman, comments: *"Preclinical data are strongly supportive of the innovative approach that MolMed has followed so far: a new target - CD44v6 - and the inclusion of a suicide gene to further limit the related potential toxicity, place MolMed at the forefront in this exciting and fast progressing field. If CAR T-cell therapy is confirmed to be curative and safe, it will probably be seen as a "game-changer", establishing this new approach as the ultimate personalised therapy, capable of defeating cancers still missing efficacious and safe treatment."*

Riccardo Palmisano, MolMed's CEO, said: *"On the basis of preclinical data collected so far, MolMed's CAR-T-cells immunotherapy clearly differentiates itself from other CAR-T projects due to its potential of increasing efficacy of immunotherapy without increasing toxicity, thus providing improved life expectancy to patients suffering from incurable haematological malignancies and from other solid tumours expressing CD44v6. MolMed will continue investing in preclinical research and development activities, in order to valorise the unique distinguishing characteristics of its project, to properly outline its place in therapy, and to drive the first in man clinical trial expected in 2018, and already funded under the EURE-CART project."*

This press release is written in compliance with public disclosure obligations established by Consob's (Italian securities & exchange commission) Issuers Regulation.

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 antitumour 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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