

Updates on the safety profile of CD44v6 CAR-T cells presented at 22nd Annual Congress of the European Haematology Association

Milan (Italy), June 25, 2017 – MolMed S.p.A. announces new safety *in vitro* data on its proprietary cancer immunogene therapy project CAR-CD44v6, presented at the 22nd Annual Congress of the European Haematology Association (Madrid, June 22-25, 2017). Dr. Attilio Bondanza, Head of Innovative Immunotherapies Unit, Division of Immunology, Transplantation and Infectious Diseases, at San Raffaele Hospital Scientific Institute, presented these data during an oral session titled "Hematology-in-Focus: New strategies in cellular therapy to prevent relapse of acute leukemia", explaining the advent of CAR-T cells therapy in the treatment of AML.

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 against tumours that 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.

However, CAR-T cells also have the capacity to elicit life-threatening toxicities including cytokine release syndrome, neurologic toxicity and potential on-target/off-tumour toxicity. Thus, 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.

Data presented at EHA Annual Congress couple with outcomes presented at the 58th Annual Meeting of the American Society of Haematology (San Diego, CA, December 3- 6, 2016), regarding the determinants of CAR-T cell efficacy and associated toxicities, that confirmed, on the subject of leukaemia, efficacy and higher safety profile of T cells *ex vivo* transduced with MolMed's CD44v6 CAR-T compared to CD19 CAR-T cells, and showed its therapeutic potential in epithelial tumours.

In particular, Dr. Bondanza presentation held in Madrid focused on the safety profile of CD44v6 CAR-T cells and showed how, although expressing the CD44v6 target at detectable levels, keratinocytes are highly resistant to CAR-T cell killing. These data suggest a wide enough therapeutic window for exploiting the anti-tumour activity of CD44v6 CAR-T cells, without incurring in unbearable skin toxicity.

Riccardo Palmisano, MolMed's CEO, said: "*Since CAR-T's potential toxicity remains one of the most critical steps to the actual application of this innovative technology, data presented in Madrid, reassuring on our CAR CD44v6 safety profile, represent a very important advancement. Preclinical studies are producing highly interesting results, confirming our CAR-CD44v6 efficacy and safety profile, both in leukaemia and solid tumours, thus helping in differentiating it versus other CAR-T projects currently under development. On the*

FROM GENES TO THERAPY

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basis of these results, we will be able to properly outline the potential of the project and thus to play a relevant role in one of the most promising fields in the treatment of tumours.”

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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