

## ***MolMed: further data on the safety profile of CAR-T CD44v6 result from a study conducted by San Raffaele Hospital, published by the prestigious journal Nature Medicine***

Milan, May 30<sup>th</sup> 2018 – MolMed S.p.A. (MLMD.MI), medical biotechnology company focusing on research, development, manufacturing, and clinical validation of Cell & Gene therapies to treat cancer and rare diseases, announces that further data on safety of CAR-T CD44v6 which investigated the safety of CAR-T-based immunotherapy in the treatment of tumours, emerged from a study conducted by researchers of IRCCS San Raffaele Hospital in Milan.

The study, led by Dr Margherita Novelli, of the Innovative Immunotherapies Unit of the IRCCS San Raffaele Hospital and coordinated by Dr Attilio Bondanza, former researcher at the Vita-Salute San Raffaele University, which was published in the latest issue of the Nature Medicine, one of the most prestigious journals in the international scientific community, highlighted the scope and potential impact of the study: making CAR-T lymphocytes based therapy much safer and workable.

The research, which was conducted by using several CAR-Ts including CAR-T CD19 (already approved by FDA) and CAR-T CD44v6, MolMed's proprietary product in an advanced preclinical phase, in fact proved the effectiveness of an approach able to control the main side effects observed in this type of therapy, namely cytokine release syndrome (CRS) and neurotoxicity.

By testing the anti-leukemic efficacy and safety of CAR-T CD19 and CAR-T CD44v6 on a new experimental animal model with a human-like immune system, researchers discovered that one of the mechanisms causing these side effects can be prevented and controlled by administering anakinra, a drug for the prevention and treatment of arthritis, currently on the market. This drug also showed that it does not affect the anti-leukemic activity of CAR-T, therefore preserving its effectiveness.

In particular, CAR-T CD44v6, confirmed its potential thanks to the high safety profile and the effectiveness already shown in previous studies in pre-clinical models *in vitro* and *in vivo*, both in leukaemia and in several solid tumours.

Claudio Bordignon, Chairman of MolMed, commented: "*The study conducted by the San Raffaele team further reinforces the therapeutic potential of MolMed's CAR-T CD44v6, which thanks to the specific antigen is able to specifically recognize a variant expressed not only by haematological malignancies, but also by some solid tumours such as breast, pancreas, head-and-neck and lung carcinomas. Findings of this new strategy on the control of side-effects further enhance MolMed's innovative approach from a safety point of view, which already benefits from the use of a suicide gene capable of limiting the potential toxicity of CAR-T therapy*".