

MolMed: AIFA granted authorization to manufacture gene therapies for marketing purposes

Milan, December 1, 2015 – MolMed S.p.A. (MLM.MI) announces that AIFA (*Agenzia Italiana del Farmaco*) granted the operating facility located in Milan, via Olgettina, 58 (at the San Raffaele Biotechnology Department - DIBIT), authorization to manufacture medicinal products to be marketed. This authorization is valid for manufacturing of medicinal products used in a specific gene therapy based on genetically modified stem cells, and in a specific cell therapy based on immune system genetic engineering, and could become operational following the outcome of the respective marketing authorization applications already submitted to EMA (European Medicines Agency).

This authorization confirms MolMed's technical-scientific and industrial quality standard in the field of gene and cell therapies, and couples with the renewal of the one granted to the same facility for manufacturing of medicinal products for investigational purposes. In fact, the production site located at DIBIT is an AIFA qualified *Officina Farmaceutica* since 2003, and is compliant with the best practices governing manufacturing of patient-specific genetically engineered cells, and active pharmaceutical ingredients for clinical use.

"We are very proud of this authorization," commented Professor Claudio Bordignon, President and CEO of MolMed S.p.A. *"because it represents a crowning achievement after years of effort and commitment dedicated to reach the highest quality levels for the development and manufacturing of ex vivo gene therapies for marketing purposes. Of course, only the marketing approval granted by the European regulatory authority for each specific therapy will make the product potentially available to a larger patient population. However, thanks to focus on innovation and technology, MolMed is the first to be ready to manufacture medicinal products of this kind for market use, both from its own or from pharma and biotech partners' pipelines."*

In 2013, MolMed started an important project aimed at expanding its production capacity at the scientific park "Open Zone" in Bresso (Milan). Once completed MolMed will have an additional fully compliant facility, meeting the same quality standards and technological expertise already endorsed at the manufacturing site located at DIBIT.

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, currently in Phase III in high-risk acute leukaemia and under evaluation by EMA for a Conditional Marketing Authorization; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood

FROM GENES TO THERAPY

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vessels feeding the tumour mass, currently investigated in a broad clinical programme; CAR-CD44v6, an immuno-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 has its headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and secondary office 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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