PRESS RELEASE

AIFA set the reimbursement price for Zalmoxis® at EUR 149.000 per infusion, gross of discounts foreseen by law, and also established a flat fee per patient

Milan (Italy), December 13, 2017 – MolMed S.p.A. (MLM.MI) is proud to announce that it obtained its first national marketing authorization for its proprietary product, Zalmoxis®: the Board of Directors of AIFA (*Agenzia Italiana del Farmaco*) approved the agreement negotiated between AIFA's Prices and Reimbursement Committee (CPR) and MolMed, in which the price and reimbursement for Zalmoxis® medicinal product were defined.

Zalmoxis® is MolMed's first patient specific cell therapy product, based on genetically engineering of the immune system, administered following haploidentical haematopoietic stem-cell transplantation (HSCT) from partially compatible donors to adult patients with leukaemia and other high-risk haematologic malignancies. Zalmoxis® is administered from the 21st day post-transplantation and foresees up to a maximum of 4 infusions per patient based on the achievement of immune-reconstitution.

The terms of the agreement provide for an *ex-factory* price, excluding VAT, of 149,000 EUR per infusion, gross of discounts foreseen by law and of selective reductions foreseen by AIFA Resolutions ("*Determinazioni*") of 3 July 2006 and 27 September 2006. Furthermore the agreement also set a flat fee per patient and a safeguard clause on sales for the first 24 months. Given the nature of the product, it will be a hospital-only dispensed therapy.

The agreement signed with AIFA will be effective from the fifteenth day subsequent to its publication in the *Gazzetta Ufficiale* of the Italian Republic.

Riccardo Palmisano, MolMed's CEO, commented: *"This is truly a turning point for a research and development company like MolMed: both Zalmoxis® eligibility for reimbursement and the "Aifa granted price" acknowledge the value of our therapy and, at the same time, the successful completion of a top level Italian research, development and manufacturing journey. In addition, this result paves the way to the marketing of this sophisticated genetically engineered cell therapy. This first national authorization allows us to look with increasing confidence to the introduction of Zalmoxis® in the other European countries covered by the Dompé agreement, from which we expect relevant results, considering our partner's value, expertise and successful track record. Zalmoxis® commercialization will allow MolMed to increase its revenues from proprietary products on top of those deriving from GMP development and production for third party."*

Professor Claudio Bordignon, Founder and Chairman of MolMed, commented*: "The inclusion of Zalmoxis® among the medicinal products reimbursable by the National Health Service makes this revolutionary therapy available to those patients for whom the allogeneic stem cell transplantation is the best treatment option for high-risk leukaemia and other blood malignancies. In absence of a fully compatible donor, Zalmoxis® makes the treatment from a haploidentical family donor safer, by eliminating post-transplant immunosuppression and, at the same time, resolving the potential occurrence of Graft versus Host Disease. Furthermore, Zalmoxis® accelerates immune-reconstitution by protecting the patient against infections and leukaemia relapse. Zalmoxis® has proven to significantly increase the one-year survival rate in the treated population."*

"We are very pleased with the outcome of MolMed's negotiation with AIFA. By stipulating this agreement, it is stated that Zalmoxis, the first ex-cell cellular therapy based on the immune system engineering for the

treatment of adult patients with high risk blood malignancies, responds to a major clinical need", commented Eugenio Aringhieri, Chief Executive Officer of Dompé. "The synergy of our distinctive competences and shared value priorities, on which this alliance with MolMed is founded, will lead us in the interaction with the scientific community and the regulatory authorities aimed at bringing Zalmoxis® to all Patients eligible for this therapy."

About Zalmoxis®

Zalmoxis® is an innovative therapy based on genetically engineering donor immune system T cells to carry an inducible "suicide gene". Administered to patients following HSCT from partially compatible donors (haploidentical HSCT), these cells foster an anti-leukaemia effect by eliminating post-transplant immunosuppression prophylaxis and inducing a rapid immune reconstitution. The suicide gene allows to readily control Graft versus Host Disease (GvHD), the most significant and serious adverse event in haplo-identical transplantation, caused by the genetic disparity between patient and donor. Zalmoxis significantly increases long-term survival, regardless of disease status at transplant, thus making HSCT from partially compatible donors safer and more effective.

On August 18th, 2016 the European Commission granted a Conditional Marketing Authorisation (CMA) for Zalmoxis®, the first immunogene therapy, as patient-specific adjunctive treatment in haplo-identical haematopoietic stem-cell transplantation for adult patients with leukaemia and high-risk haematological malignancies. Following this authorization, which allows MolMed to market Zalmoxis® in the 28 EU Member States and in the European Economic Area, activities aimed at its introduction on the European markets have increased. The marketing authorization issued by AIFA is therefore only the first out of the ones on which MolMed has been working since the date of the European CMA.

With the aim of successfully marketing Zalmoxis®, on July 26th, 2017 MolMed signed an exclusive license and distribution agreement with Dompé Farmaceutici S.p.A., one of the leading Italian biopharmaceutical companies, granting Dompé the exclusive right and obligation to conduct all activities aimed at promoting, marketing, exploiting, distributing and selling Zalmoxis® in all member countries of the current European Economic Area (EEA) and an option right for Switzerland, Turkey and Australia.

In parallel, preparation of the dossier to obtain price and reimbursement of Zalmoxis® from the German and French authorities continued through direct interactions. Furthermore activities aimed at starting negotiations with authorities of other countries have been speeded up. In regard to distribution and marketing beyond the European borders, contracts have already been signed with Megapharm Ltd for Israel and with TTY Biopharm Company Ltd for Taiwan and a number of countries in South-East Asia.

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 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 is 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 manufacturing of viral vectors and patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and an operating unit at OpenZone in Bresso (Milan, Italy). MolMed is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana (Reuters: MLMD.MI).

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