



PRESS RELEASE

## ***MolMed announces the decision to suspend the enrollment of new patients in phase III study TK008 with Zalmoxis®.***

Milan (Italy), June 27<sup>th</sup> 2019 - MolMed S.p.A. (MLMD.MI), a biotechnology company focused on research, development, production and clinical validation of gene and cell therapies for the treatment of cancer and rare diseases, announces the suspension of the enrollment of new patients in the phase III clinical trial with Zalmoxis® named TK008.

In reviewing the product development plan, the Company decided to conduct an unplanned interim analysis on the first 90 patients included in the study, representing approximately 50% of the total number of patients required by the protocol. This analysis, although not conclusive, has not shown an advantage of the arm treated with Zalmoxis® compared to the control arm treated with the standard of care, with reference to the primary endpoint of the study, namely disease-free survival.

The Company is now in the process of completing the available data analysis and interacting with the Regulatory Authorities and the centers involved in the clinical trial in order to define the next steps of the study and the future development of the product.

### ***About MolMed***

MolMed S.p.A. is a clinical stage biotech company focused on research, development, manufacturing and clinical validation of innovative therapies. MolMed's product portfolio includes proprietary anti-tumor therapies in both clinical and preclinical development: Zalmoxis® (TK) is a cell therapy based on donor T cells genetically engineered to enable bone marrow transplants from partially compatible donors for patients with high-risk hematological malignancies, eliminating post-transplant immunosuppression prophylaxis and inducing a rapid immune reconstitution. Zalmoxis®, that received orphan drug designation and utilized in Phase III in a high-risk population of acute leukemia patients, has obtained a Conditional Marketing Authorization by the European Commission in the second half of 2016 as well as reimbursement conditions in Italy and in Germany at the beginning of 2018. Still focusing on this cell & gene technology, the Company is developing a new therapeutic platform based on Chimeric Antigen Receptor (CAR), both autologous and allogeneic; the most advanced product, CAR-T CD44v6, which on March 2019 received the authorization to start human clinical trials in onco-hematologic indications (AML and MM), following an extensive pre-clinical phase; the product is potentially effective also in several epithelial solid tumors. With regards to allogeneic CARs, MolMed is developing a pipeline based on NK (Natural Killer) cells, following a research agreement signed in 2018 with Glycostem. MolMed is also the first company in Europe to have obtained the GMP manufacturing authorization for cell & gene therapies for its proprietary products (Zalmoxis®) as well as for third parties and/or in partnership (Strimvelis, an Orchard gene therapy for the ADA-SCID). With reference to GMP development and manufacturing activities for third parties, MolMed signed numerous partnership agreements with leading European and US companies. In the field of innovative oncological therapies MolMed pipeline also includes NGR-hTFN, a therapeutic agent for the treatment of solid tumors. MolMed, founded in 1996 as an academic spin-off of the San Raffaele Scientific Institute, is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana since March 2008. MolMed is headquartered and based in Milan, at the San



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Raffaele Biotechnology Department (DIBIT) and has an operating unit at OpenZone in Bresso.

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