



PRESS RELEASE

MolMed: opinion of the Transparency Commission of the French National Health Authority (HAS) on Zalmoxis® reimbursability in France.

Milan (Italy), January 15th, 2019 – MolMed S.p.A. (MLMD.MI), clinical stage biotechnology company focusing on research, development, manufacturing and clinical validation of cell & gene therapies for the treatment of cancer and rare diseases, announces that the Transparency Commission of the French National Health Authority (HAS), conveyed a non-favourable opinion concerning the reimbursability of the orphan drug Zalmoxis® in the therapeutic indications granted by EMA (European Medicines Agency). The Commission considered that the submitted phase I and II data are currently not sufficient to justify a reimbursement by the French healthcare system.

Riccardo Palmisano, MolMed's CEO commented: *"We are obviously disappointed by this position, which we fully respect, even if it completely diverges from the opinion undertaken by Italy and Germany, two main countries that, following the marketing authorization obtained from EMA for the 28 EU member states, granted the reimbursability of Zalmoxis®. On our side, we continue to invest in the development of the product to reinforce its clinical data, confident that the new clinical evidence will also convince the transalpine authorities in the future"*.

This press release is available on the Company's website <http://www.molmed.com>

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 is currently in Phase III in a high-risk population of acute leukemia patients, but has already 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, is looking forward to obtain 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



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

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