PRESS RELEASE



## MolMed: Germany confirms the reimbursement of Zalmoxis<sup>®</sup> at a price of 130,000 Euro per infusion.

Milan (Italy), February 4<sup>th</sup>, 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, is pleased to announce that the German public health insurance system (GKV) has approved the reimbursement of Zalmoxis<sup>®</sup> at a price of 130,000 Euros per infusion (ex-factory price excluding VAT). The cost per patient will be based on the approved dosing schedule, which allows from 1 to 4 infusions, until the immune-reconstitution is reached, and on the clinical experience, that shows an average of just over 2 infusions per patient.

The agreement will be in force as of February 15<sup>th</sup>, 2019 and follows the authorization granted in February 2018 and the consequent drug evaluation and price negotiation process regulated by the AMNOG system, according to which the G-BA Federal Committee recognized to MolMed's therapy a benefit for the treatment of adult patients with high risk relapse leukemia in haplo-identical haematopoietic stem cell transplantation (haplo-HSCT).

Thanks to this agreement, valid for the next 24 months, Zalmoxis<sup>®</sup> could be prescribed not only in the 2 transplant centres authorized hitherto, but in all the bone marrow transplant centres operating in Germany.

Riccardo Palmisano, MolMed's CEO commented: "We are very glad for this result, obtained after a rigorous evaluation process and an in-depth discussion with representatives of the German public health insurance system, which once again confirms the therapeutic value of Zalmoxis. This new recognition reinforces our search for a new commercial partner, after the return of the commercial rights for all European countries to MolMed last year in mid-November".

## 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



PRESS RELEASE

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

For further information:

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