

Zalmoxis®: price & reimbursement dossier filed in Germany, where the product can be prescribed and reimbursed as of January 15th

Milan (Italy), January 16th 2018 – MolMed S.p.A. ("MolMed") announces that Dompé farmaceutici S.p.A. ("Dompé"), Zalmoxis®'s licensee for Europe, has submitted the AMNOG file (Gesetz zur Neuordnung des Arzneimittelmarkt) for this product to the Federal Joint Committee (Gemeinsamer-Bundesausschuss G-BA).

Following filing of the dossier and publication of the price on the Lauer-Taxe® (the official price database for drugs), as of January 15th Zalmoxis® can be prescribed and reimbursed in Germany at the submitted price of 163,900 EUR per infusion (ex-factory price, VAT excluded). The approved dosage foresees one or more infusions, up to a maximum of four, till immune-reconstitution is achieved. These conditions are valid for twelve months during which, according to the AMNOG model and as indicated on the G-BA website, the additional benefits of the innovative therapy for patients will be assessed and, on this basis, lead to the final price negotiation.

Under the terms and conditions of the license and distribution agreement for all the European countries signed in July 2017, MolMed will be responsible for production and supply of Zalmoxis®, while Dompé will conduct all activities aimed at promoting and marketing the therapy in Germany and will accord MolMed a purchase price proportional to the reimbursed price of the product.

Zalmoxis® is MolMed's first patient-specific immunogene therapy based on genetically engineering of the immune system as adjunctive treatment in haplo-identical haematopoietic stem-cell transplantation for adult patients with leukaemia and high-risk haematological malignancies.

Riccardo Palmisano, MolMed's CEO, commented: *"Entering the German market is a new and important milestone for Zalmoxis® and our Company, just one month after approval of the price and reimbursement by AIFA, the Italian Medicines Agency, in Italy whose publication in the Gazzetta Ufficiale of the Italian Republic is expected soon. Zalmoxis® can now also be prescribed, used and reimbursed in the largest European market. As planned, we are pursuing the development of our business model, which envisages on the one hand the growing exploitation of our proprietary products stemming from our research, such as Zalmoxis®, and on the other the continuous development of cell & gene GMP production for third parties."*

"That's excellent news for those German patients who are candidate for an allogeneic transplant for the treatment of high risk hematologic malignancy, but are lacking a fully matched donor and who are, therefore, candidates for this innovative therapy", commented Professor Claudio Bordignon, Founder and Chairman of MolMed. *"With the introduction of Zalmoxis® in Germany an ever increasing number of patients will benefit from this new therapeutic solution"*.

"We share great satisfaction for the introduction of Zalmoxis® in Germany", commented Eugenio Aringhieri, CEO of Dompé. *"It represents a significant step forward for German patients who, as of today, have a possible solution to an important health need. This achievement strengthens the value of our partnership with MolMed, based on innovation. We are expecting the therapy to soon become available for all Italian patients"*.

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.

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 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.



PRESS RELEASE

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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