

The European Commission grants a Conditional Marketing Authorisation to Zalmoxis[®], the first immunogene therapy for the treatment of adult patients with high-risk haematological malignancies:

- *Clinical benefit of Zalmoxis in addressing a significant patient unmet therapeutic need confirmed*
- *MolMed leadership in the immunogene therapy of cancer recognized*
- *Access to European market speeded up: first price & reimbursement authorisation planned within the first half of 2017 and interest of potential partners in in-licensing Zalmoxis for the European market under evaluation*
 - *Detailed analysis of data provided for CMA will be presented at the 1^o EBMT International Transplant Course (Barcelona, Sept. 9 -11, 2016) -*

Milan (Italy), August 22, 2016 – MolMed S.p.A. announced today that the European Commission has granted a Conditional Marketing Authorisation (CMA) for Zalmoxis, the first immunogene therapy, as patient-specific adjunctive treatment in haplo-identical haematopoietic stem-cell transplantation (HSCT) for adult patients with high-risk haematological malignancies.

It is estimated that in the EU approximately 1,300¹ high-risk haematological malignancies patients per year undergo haplo-identical HSCT, growing 30%¹ annually. In addition, almost 11,000¹ patients with high-risk haematological malignancies are candidate for allogeneic transplant and lack a fully compatible donor, for whom Zalmoxis might represent a viable therapeutic solution.

Zalmoxis innovative therapy is based on genetically engineering donor immune system T cells to carry an inducible “suicide gene”. Administered to patients following HSCT from partially compatible donors (haplo-identical HSCT), these cells foster an anti-leukemia effect by eliminating post-transplant immunosuppression prophylaxis and inducing a rapid immune reconstitution. The suicide gene allows to readily control Graft versus

¹ Source: 2014 market data reported by 2016 EBMT registry.

FROM GENES TO THERAPY

MOLMED S.p.A.

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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.

The Summary of Product Characteristics (SmPC) will include the full prescribing information, including the safety and efficacy profile of Zalmoxis in the approved indication. The SmPC, which will be published in the European Public Assessment Report (EPAR), is expected to be posted to the European Medicines Agency's (EMA) website in the next few weeks.

The CMA decision was based on cumulative efficacy and safety data collected from patients enrolled in the Phase I-II trial (TK007) and in the currently ongoing pivotal randomised Phase III study (TK008).

The Zalmoxis group comprised 30 patients from the TK007 trial and 15 patients from the experimental arm of the ongoing TK008 trial. The TK007 trial included patients with various types of high-risk hematologic malignancies, while the TK008 trial is enrolling patients with acute myeloid or lymphoblastic leukaemia in any complete remission or advanced-stage disease, or with secondary acute myeloid leukemia.

The data showed the ability of Zalmoxis in providing patients undergoing haploidentical transplantation with rapid immune reconstitution, anti-leukaemia effect and complete control of GvHD, in absence of any post transplantation immunosuppression. Overall, these effects led to a clinically meaningful increase in survival rates in Zalmoxis-treated patients, when compared to historical control patients from the database of European Group for Blood and Marrow Transplantation (EBMT) Society. Currently, there are neither approved therapy nor widely accepted standard of care able to overcome the two problems that continue to account for most of the non-relapse deaths, opportunistic infections and GVHD, as well as to increase survival rates after haploidentical HSCT. Importantly, the comparison with control patients confirmed that the survival improvement in Zalmoxis-treated patients was specifically driven by a reduction in mortality due to both infection and GvHD. Concerning safety, the only adverse event related to Zalmoxis treatment was GvHD, which fully resolved by the activation of the suicide gene system with ganciclovir treatment, without any GvHD-related death.

Detailed results of this analysis will be presented at the forthcoming 1° EBMT International Transplant Course (Barcelona, Sept. 9 -11), during a symposium titled "A new era of haplo-transplantation" sponsored by MolMed".

Following CE authorisation, patients found eligible will receive treatment with Zalmoxis through dedicated centres of excellence and TK cells will be manufactured at MolMed's facilities, located at the San Raffaele Biotechnology Department (DIBIT) in Milan and at Open Zone scientific park in Bresso (Milan), where MolMed has recently completed a new manufacturing site, which will substantially increase the current production capacity, waiting for gradual AIFA authorisation by the end of 2016.

Professor Claudio Bordignon, Chairman of MolMed S.p.A., commented: *"This is the most important milestone of a long journey, begun 20 years ago. This is the dreamed destination of a path made of resilience and passion, tracked while investigating what we consider the most promising field of cancer treatment: the immunogene therapy. Our researchers' pioneering approach made MolMed a leader in the immunogene therapy of cancer and data that supported EC's decision, confirming Zalmoxis capability of enabling a safer haploidentical transplant in patients lacking a matched donor, represent a unique and incomparable outcome:*

in fact, their strength and reliability are sustained by one of the largest immunogene therapy of cancer program developed so far, and by the comparison with historical data provided by the largest available bone marrow transplantation database, actually the best available proxy to the “real life” experience in the field”.

Riccardo Palmisano, CEO of MolMed S.p.A., said: *“The Conditional Marketing Authorization, allowing MolMed to market Zalmoxis in all 28 EU Member States as well as into the European Economic Area, will speed up the introduction of this innovative new therapy to patients with unmet medical need. The EC’s decision for Zalmoxis is an important milestone for adult patients with high-risk haematological malignancies and we are doing our best in order to make this product soon available for patients in the EU, but not only. Actually, in the first half of 2016, we started preparatory activities to support price & reimbursement negotiations and we are currently evaluating the interest of potential partners in in-licensing Zalmoxis for the European market. We already started discussion with German authorities, thus we plan to access the first European market during the first half of 2017. Furthermore, in the light of the successful experience with European authorities, we are considering to start activities to request accelerated access at FDA. We are all aware of the relevance/significance of this tremendous achievement for patients, for MolMed and for its shareholders: it represents a real turnaround point for the life of our Company and we’ll make every efforts to exploit it for the future growth of MolMed, by combining our well-known R&D and manufacturing capabilities with commercial activities.”*

About TK008

TK008 is a pivotal randomised Phase III trial in adult patients affected by high-risk leukaemias undergoing HSCT from partially compatible family donors (haplo-identical HSCT). The trial design has a 3:1 randomisation ratio in favour of the Zalmoxis arm and disease-free survival as the primary end-point - which includes both transplant-related mortality and disease relapse - evaluated in 170 patients. The trial compares the outcome of haplo-identical HSCT with or without Zalmoxis. Secondary end-points include overall survival, reduction of transplant-related mortality, safety and patient quality of life. With the aim to provide additional clinical benefit to patients and to significantly increase the potential participation of centres in the trial, the Company implemented in 2012 two important changes in TK008 protocol design. The first broadens the enrolment criteria including patients in leukemic relapse, in addition to those in disease remission; the second includes a further treatment option in the control arm, based on the use of an unmanipulated transplant followed by cyclophosphamide administration during the post-transplantation period.

About Conditional Marketing Authorisation

The Conditional Marketing Authorisation represents an expedite path for early market authorisation ahead of completion of the pivotal registration studies. Such anticipated authorisation is granted to medical products with a positive risk/benefit assessment that address unmet needs and whose availability would result in a significant public health benefit. Under the provisions of the conditional marketing authorisation for Zalmoxis, MolMed will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed. The CHMP has accepted TK008 trial as post-marketing confirmatory study.

For more information, visit the EMA website at <http://www.ema.europa.eu>.

This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14 May 1999, as subsequently amended.

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 by CE for a Conditional Marketing Authorisation; 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, an immunogene 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 production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells. MolMed has its headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and a local unit at OpenZone, in Bresso (Milan). MolMed is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana (ticker Reuters: MLMD.MI).

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