EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/CHMP/380467/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zalmoxis

allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)

On 23 June 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Zalmoxis, intended as adjunctive treatment in haploidentical haematopoietic stem cell transplantation (HSCT) of adult patients with high-risk haematological malignancies. Zalmoxis was designated as an orphan medicinal product on 17 September 2003. As Zalmoxis is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies. The applicant for this medicinal product is MolMed SpA.

Zalmoxis will be available as dispersion for infusion. The active substance of Zalmoxis is made of allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2). The genetically modified T cells are given to transplant patients to help the body fight off infection, enhance the success of the transplant and support long-lasting anti-cancer effects; however T cells can also cause graft-versus-host disease. A suicide gene in the modified T cells makes them susceptible to ganciclovir or valganciclovir. If the patient develops graft-versus-host disease, ganciclovir/valganciclovir is given, which kills the modified T cells that have the suicide gene, so preventing further development of the disease.

The benefits with Zalmoxis are its ability to increase overall survival rates: data in 45 patients treated with Zalmoxis showed that survival rate was 49% after one year with Zalmoxis, compared with data from databases of 140 patients who had undergone haploidentical HSCT without Zalmoxis, where survival rate was 37%.

The most common side effect was acute graft-versus-host disease.

The full indication is: "Zalmoxis is indicated as adjunctive treatment in haploidentical haematopoietic stem

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

cell transplantation (HSCT) of adult patients with high-risk haematological malignancies". It is proposed that Zalmoxis be prescribed by physicians experienced in the haematopoietic stem cell transplantation for haematological malignancies.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.