17 September 2020
EMA/CHMP/449146/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Phelinun

melphalan

On 17 September 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Phelinun, intended for the treatment of certain haematological and other cancers and as reduced intensity conditioning (RIC) treatment prior to allogeneic haematopoietic stem cell transplantation (allo-HSCT) in haematological diseases in adults and children.

The applicant for this medicinal product is ADIENNE S.r.l. S.U.

Phelinun will be available as 50-mg and 200-mg powder and solvent for concentrate for solution for infusion. The active substance of Phelinun is melphalan, an anti-neoplastic agent (ATC code: L01AA03) which prevents the separation and replication of DNA, thereby preventing cell replication.

The benefits of Phelinun from published studies in adults and children include increased overall survival (OS), disease-free survival (DFS), event-free survival (EFS) and non-relapse mortality (NRM). The most common side effects are myelosuppression and haematological toxicities, gastrointestinal toxicity and immune system disorders. Amenorrhoea, ovarian disorders and premature menopause were also commonly reported. Infections, acute and chronic graft-versus-host disease (GvHD) were reported as the major causes of morbidity and mortality in the allo-HSCT setting. Phelinun is a hybrid medicine[2] of Alkeran which has been authorised in the EU since 1996. Phelinun contains the same active substance as Alkeran but is intended for an additional indication based on published literature.

Studies have demonstrated the satisfactory quality of Phelinun. Since Phelinun is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Alkeran was not required.

The full indications are:

> High-dose of PHELINUN used alone or in combination with other cytotoxic medicinal products and/or total body irradiation is indicated in the treatment of:

[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] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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- multiple myeloma,
- malignant lymphoma (Hodgkin, non-Hodgkin lymphoma),
- acute lymphoblastic and myeloblastic leukemia,
- childhood neuroblastoma,
- ovarian cancer,
- mammary adenocarcinoma.

PHELINUN in combination with other cytotoxic medicinal products is indicated as reduced intensity conditioning (RIC) treatment prior to allogeneic haematopoietic stem cell transplantation (allo-HSCT) in malignant haematological diseases in adults.

PHELINUN in combination with other cytotoxic medicinal products is indicated as conditioning regimen prior to allogeneic haematopoietic stem cell transplantation in haematological diseases in the paediatric population as:

- Myeloablative conditioning (MAC) treatment in case of malignant haematological diseases
- RIC treatment in case of non-malignant haematological diseases.

Phelinun should be prescribed by physicians experienced in the treatment of cancer.

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.