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Press Office

Press release

European Medicines Agency recommends approval of fourth advanced therapy in Europe

New advanced therapy for treatment of metastatic prostate cancer cleared by CAT and CHMP for marketing authorisation

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for a new advanced-therapy medicinal product (ATMP). Provenge is recommended for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant prostate cancer in male adults in whom chemotherapy is not yet clinically indicated.

ATMPs are innovative medicines that are derived from gene therapy, cell therapy or tissue engineering. The CHMP recommendation follows the draft opinion of the Committee for Advanced Therapies (CAT), the Agency's expert committee for ATMPs.

Provenge is the fourth ATMP which has been recommended for marketing authorisation by the CHMP since the legislation on advanced therapies became operational. The other three are Glybera, the first gene therapy authorised in Europe (in 2012), and the tissue-engineered products ChondroCelect (in 2009) and MACI (in 2013).

Prostate cancer is the most common cancer in men; it affects one in six men and is the second leading cause of cancer deaths among males in most Western countries. Metastatic prostate cancer is the leading cause of prostate cancer-related death and the disease cannot be cured by currently available therapies. The median survival in these patients is one to three years.

Provenge is a cellular immunotherapy designed to induce an immune response against prostate cancer cells. Provenge uses immune cells which are extracted from and treated outside the patient's body so that, when they are infused back into the patient, they trigger an immune response directed against an antigen found in metastasised cancer cells.

Provenge has been shown to improve the overall survival by 4.1 months over placebo in clinical trials. Because it is an immunotherapy it is considered less toxic than the therapies currently available for this indication. Therefore, the CHMP concluded that the benefits of Provenge outweigh its risks and recommended its marketing authorisation.

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The CHMP and CAT have worked closely together in the evaluation process for Provenge. Both committees have distinct responsibilities in the approval process of advanced-therapy medicines. The CAT adopts a draft opinion, which is taken into account by the CHMP when giving its recommendation regarding the authorisation of a medicine in view of the balance of benefits and risks identified.

The marketing-authorisation holder for Provenge is Dendreon.

The applicant received scientific advice from the CHMP which pertained to quality and clinical aspects of the dossier.

The CHMP opinion on Provenge will now be sent to the European Commission for adoption of a marketing-authorisation decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The common name of Provenge is autologous peripheral blood mononuclear cells activated with PAP-GM-CSF (sipuleucel-T).
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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