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Press Office

Press release

European Medicines Agency recommends extending use of Abraxane to include treatment of pancreatic cancer

New indication offers treatment option for patient population with unmet medical need

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended adding the treatment of patients with metastatic pancreatic cancer to the approved indications for Abraxane.

In Europe, pancreatic cancer is the fifth leading cause of cancer-related death, with almost 100,000 deaths every year. Over 99% of affected patients die of their disease. Across all stages of pancreatic cancer, the five-year survival rate is about 5%. This rate falls to 1.6% in patients with metastatic disease.

The CHMP has recommended the approval of Abraxane in combination with gemcitabine, another cancer medicine which is currently the standard therapy in the first-line treatment of adults with metastatic pancreatic cancer.

This recommendation offers an additional treatment option for patients who suffer from a type of cancer for which no medicine has been approved since 2007.

The combination of Abraxane with gemcitabine has been shown in clinical trials to prolong the lives of patients with metastatic pancreatic cancer by 1.8 months. In its assessment, the CHMP considered that the improvement in overall survival was a clinical benefit that outweighed the risks of adverse events.

Abraxane contains the active substance paclitaxel. This substance belongs to the group of anticancer medicines known as taxanes, which block a stage of cell division causing the cells to die. In Abraxane, the active substance paclitaxel is attached to a human protein called albumin to allow the preparation of an injectable suspension.

Abraxane was authorised throughout the European Union in January 2008 for the treatment of metastatic breast cancer in adults whose first treatment has stopped working and for whom standard treatment is not suitable.

The marketing authorisation holder for Abraxane is Celgene Europe Limited.

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The CHMP opinion on the new indication for Abraxane will now be sent to the European Commission for adoption of a decision on a variation to the terms of the marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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