21 July 2016
EMA/CHMP/478619/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Onivyde

Irinotecan (pegylated liposomal formulation)

On 21 July 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Onivyde, intended for the treatment of metastatic adenocarcinoma of the pancreas. Onivyde was designated as an orphan medicinal product on 9 December 2011. The applicant for this medicinal product is Baxalta Innovations GmbH.

Onivyde will be available as a concentrate for solution for infusion (5.0 mg/ml). The active substance of Onivyde is irinotecan, a topoisomerase I inhibitor (ATC code: L01XX19) which binds reversibly to the topoisomerase I DNA complex and induces single strand DNA lesions blocking the DNA replication fork. Onivyde contains irinotecan in a pegylated liposomal formulation.

When added to 5-fluorouracil (5-FU) 2,400 mg/m^2 and leucovorin (LV) 400 mg/m^2, Onivyde improved survival compared with 5-FU 2,000 mg/m^2 and LV 200 mg/m^2. The most common side effects are diarrhoea, nausea, vomiting, decreased appetite, neutropenia, fatigue, asthenia, anaemia, stomatitis and pyrexia.

The full indication is: "Treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), in adult patients who have progressed following gemcitabine based therapy." It is proposed that Onivyde be prescribed by physicians experienced in the use of anti-cancer therapies.

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.

[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

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