EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2011
EMA/27541/2011 – Correction 1[1]*
Committee for medicinal products for human use (CHMP)

Summary of opinion[2] (initial authorisation)

Halaven

Eribulin

On 20 January 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Halaven, 0.44 mg/ml solution for injection, intended for treatment of patients with breast cancer who have received at least two chemotherapeutic regimens for locally advanced or metastatic disease. The applicant for this medicinal product is Eisai Europe Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Halaven is eribulin mesylate, an antineoplastic agent (L01XX41). Halaven inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into nonproductive aggregates. Eribulin exerts its effects via a tubulin-based antimitotic mechanism leading to G_2/M cell-cycle block, disruption of mitotic spindles, and, ultimately, apoptotic cell death after prolonged mitotic blockage.

The benefits with Halaven as a late line treatment in patients with advanced breast cancer are in terms of survival and progression-free survival compared to the treatment of physician's choice. The most common side effects are neutropenia/leukopenia, asthenia/fatigue, nausea, constipation, alopecia, arthralgia/myalgia, pyrexia and peripheral neuropathy.

A pharmacovigilance plan for Halaven will be implemented as part of the marketing authorisation.

The approved indication is: "HALAVEN monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments."

It is proposed that Halaven is prescribed by physicians experienced in the in the appropriate use of cytotoxic medicinal products.

[1] * Corrected INN and dose.
[2] 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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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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Halaven and therefore recommends the granting of the marketing authorisation.