8 July 2016
EMA/459461/2016

PRAC concludes review of Zydelig and issues updated recommendations for use

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed its review of Zydelig (idelalisib), confirming that the medicine's benefits outweigh its risks in the treatment of two types of blood cancers, chronic lymphocytic leukaemia (CLL) and follicular lymphoma. The PRAC however confirmed that there is a risk of serious infections with Zydelig, including *Pneumocystis jirovecii* pneumonia and has updated recommendations to manage this risk issued at the beginning of the review.[1]

The review was started after a higher rate of serious adverse events related to infections, such as pneumonia, was seen in three clinical trials among patients who received either Zydelig or placebo (a dummy treatment) in addition to other cancer medicines. Although the studies did not use the medicine in the same way as currently authorised, the risk of serious infection is considered relevant to the authorised use and the PRAC recommends that all patients treated with Zydelig should be given antibiotics to prevent *Pneumocystis jirovecii* pneumonia during treatment and for up to 2 to 6 months after treatment has stopped. Patients should also be monitored for infection and have regular blood tests for white cell counts because low counts can increase their risk of infection. Zydelig should also not be started in patients with a generalised infection.

At the beginning of the review the PRAC had advised as a precaution not to start Zydelig in patients with previously untreated CLL whose cancer cells have certain genetic mutations (17p deletion or TP53 mutation). The PRAC now concludes that Zydelig can again be initiated in these patients provided they cannot take any alternative treatment and that the measures agreed to prevent infection are followed.

The PRAC's recommendations will now be passed to EMA's Committee for Medicinal Products for Human Use (CHMP) for adoption of the Agency's final position.

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/03/news_detail_002490.jsp&mid=WC0b01ac058001d126

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More about the medicine

In the EU, Zydelig is authorised for the treatment of:

- chronic lymphocytic leukaemia in patients who have received previous treatment as well as in previously untreated patients who have certain genetic mutations in their cancer cells (17p deletion or *TP53* mutation) that make them unsuitable for treatment with a combination of chemotherapy medicines and immunotherapy (treatments that stimulate the immune system to kill cancer cells). It is used in combination with rituximab;
- a type of non-Hodgkin's lymphoma called follicular lymphoma where it is used on its own.

More information on the approved uses of Zydelig can be found here.

More about the procedure

The review of Zydelig was initiated at the request of the European Commission on 11 March 2016, under Article 20 of Regulation (EC) No 726/2004.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. The PRAC recommendations will now be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

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