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Press Office

Press release

PRAC updates on the risks of serious vascular occlusive events associated with cancer medicine Iclusig

Modification of product information under way to include strengthened warnings

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC), at its November 4-7 meeting, has reviewed new information on the cancer medicine Iclusig (ponatinib) that suggests that side effects such as vascular occlusive events (blood clots obstructing the arteries or veins) occur at a higher rate than initially observed at the time of granting the EU marketing authorisation in July 2013.

Conditions related to thrombosis such as myocardial infarction (heart attack) are known side effects of Iclusig and the current EU product information mentions the risk of myocardial infarction, cerebral infarction (stroke), and related disorders.

The PRAC advice is that patients and healthcare professionals may continue to use this medicine with increased caution in its authorised use and should monitor carefully for evidence of thromboembolism (formation of blood clots in the veins and arteries) and vascular occlusion.

Iclusig is an anticancer medicine belonging to the class of tyrosine kinase inhibitors, used to treat patients with chronic myeloid leukaemia and Philadelphia-chromosome positive acute lymphoblastic leukaemia. In the European Union, since the initial approval, the medicine's use had been limited to patients who had no other available treatment options with medicines of this class, for example because they were intolerant to other medicines of this class or their disease was resistant to such treatment.

The PRAC has advised that the product information should be updated to include strengthened warnings on the cardiovascular risk and guidance on optimising the patient's cardiovascular therapy before starting treatment. This advice will now be considered by the Agency's Committee for Medicinal Products for Human Use (CHMP), in the context of an ongoing procedure started on 24 October 2013 to update the product information of this medicine. The CHMP is expected to issue an opinion during its next meeting, which will take place from 18-21 November.

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In addition to changes in the product information, the PRAC also highlighted the need to carry out an in-depth review of the medicine's benefit-risk profile.

About Iclusig

Iclusig is indicated in the European Union in adult patients with:

- chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation
- Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: <LINK>
2. The marketing authorisation holder for this medicine is Ariad.
3. Iclusig is an orphan medicinal product.
4. Iclusig is currently commercialised in Austria, France, Germany, Luxembourg, the Netherlands, the United Kingdom
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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