



November 5, 2014

Re: continued availability of ponatinib (Iclusig®) via Named Patient Program until at least June 2015

Dear doctor,

With this letter, we'd like to inform you about the continued availability of ponatinib (Iclusig®) in Belgium via a Named Patient Program. This is for new patients and for patients who were already enrolled in the program.

On July 1st, 2013 the European Commission granted approval of ponatinib (Iclusig®), a tyrosine kinase inhibitor for the treatment of 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.

On October 24 the European Medicines Agency (EMA) has confirmed the positive benefit/risk ratio for ponatinib, after a thorough review of all currently available safety and efficacy data.

We plan to submit the ponatinib reimbursement dossier to the Belgium authorities in December. Since the review will take at least 6 months, we expect that ponatinib will not be commercially available before July 2015.

To help make sure that CML and Ph+ ALL patients in Belgium who are in need of ponatinib have a chance to benefit from the drug, ARIAD will continue to make ponatinib available through a Named Patient Program (NPP).

(continued)



Details of this program are as follows:

- The ponatinib NPP is available for patients within the EU licensed indication
- The program will continue until at least June 30, 2015
- June 30, 2015 would then be the last date that a 1-month resupply request can be accepted
- Requests for ponatinib can be submitted by fax to 02 401 28 09. This fax number will automatically generate an email to MASF@idispharma.com and ARIAD. You will then receive a patient entry form and other relevant information. The IDIS team can also be contacted directly via e-mail at MASF@idispharma.com or by phone at +44 32824123.

For patients participating in the NPP, we are kindly asking you to document essential inclusion data and efficacy and safety parameters. ARIAD has hired the services of a CRO (XPE) to review and analyze the data that have been collected. These data can provide further insight in the experience with ponatinib in Belgium and support the reimbursement authorities when reviewing available evidence.

With the NPP, we are collaborating with the MyeloProliferative Neoplasms committee of the Belgium Hematological Society. Members of the committee are available as consultants to provide ponatinib treatment advice.

Should you have questions related to ponatinib or the Named Patient Program, do not hesitate to contact us by phone or e-mail (see details below).

Thank you in advance for your continued support.

With kind regards,

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