DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203469/S-029

SUPPLEMENT APPROVAL

ARIAD Pharmaceuticals, Inc.
Attention: Eileen Bedell, MPH
Senior Director, Regulatory Affairs
40 Landsdowne Street
Cambridge, MA 02139

Dear Ms. Bedell:

Please refer to your Supplemental New Drug Application (sNDA) dated May 18, 2018, received May 18, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Iclusig® (ponatinib) Tablets, 15 mg, 30 mg, 45 mg.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated December 20, 2016.

This Prior Approval supplemental new drug application proposes modification to the approved Iclusig REMS. This supplement is in response to our May 8, 2018, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Iclusig was originally approved on December 20, 2013, and the most recent REMS modification was approved on November 28, 2016. The REMS consists of a communication plan, and a timetable for submission of assessments of the REMS. To minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification letter dated May 8, 2018.

Communication Plan: We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Iclusig outweigh its risks because the communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goals. No further assessments are necessary to assess the current communication plan.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Iclusig.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Diane Leaman, Safety Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Barry W. Miller
Deputy Director for Safety, acting
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BARRY W MILLER
05/29/2018