4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5344]

Pharmacyclics LLC.; Withdrawal of Approval of Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma for IMBRUVICA (ibrutinib) Capsules and Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for mantle cell lymphoma (MCL) and marginal zone lymphoma (MZL) for IMBRUVICA (ibrutinib) Capsules and Tablets approved, respectively, under new drug applications (NDAs) 205552 and 210563. These NDAs are held by Pharmacyclics LLC, 1000 Gateway Blvd., South San Francisco, CA 94080 (Pharmacyclics). Pharmacyclics voluntarily requested that the Agency withdraw approval of these indications and waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On November 13, 2013, FDA approved NDA 205552 for IMBRUVICA (ibrutinib) Capsules for the treatment of adult patients with MCL who have received at least one prior therapy (the MCL indication). On January 18, 2017, FDA approved a prior approval supplement for NDA 205552 for IMBRUVICA (ibrutinib) Capsules for the treatment of adult patients with MZL who require systemic therapy and have received at least one prior anti-CD20-based therapy (the MZL indication). On February 16, 2018, FDA

approved NDA 210563 for IMBRUVICA (ibrutinib) Tablets, a new dosage form of IMBRUVICA (ibrutinib), for the MCL and MZL indications. FDA approved the MCL and MZL indications for both products under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of IMBRUVICA (ibrutinib) Capsules and Tablets for the MCL and MZL indications, the applicant was required to conduct postmarketing trials to verify the clinical benefit of ibrutinib for the MCL and MZL indications.

On February 8, 2023, FDA met with Pharmacyclics to inform the applicant of the plans to convene the Oncologic Drugs Advisory Committee regarding the accelerated approvals for the MCL and MZL indications because the required postmarketing trials did not verify the clinical benefit of ibrutinib for these indications. On March 21, 2023, FDA met with Pharmacyclics to discuss the applicant's request to voluntarily withdraw approval of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets. On April 6, 2023, Pharmacyclics submitted a letter requesting withdrawal of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing.

Therefore, under § 314.150(d), approvals of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets are withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Withdrawal of approval of these indications does not affect any other approved indication for IMBRUVICA (ibrutinib) Capsules and Tablets.

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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