Dated: December 11, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–27655 Filed 12–15–23; 8:45 am]

**BILLING CODE 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**DATES:** Approval is withdrawn as of December 18, 2023.

**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 December 18, 2023. 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Funding Opportunity for the Community Opioid Intervention Prevention Program

*Announcement Type:* New.

*Funding Announcement Number:* HHS–2024–IHS–COIPP–0001.

*Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:* 93.654.

#### Key Dates

*Application Deadline Date:* February 7, 2024.

*Earliest Anticipated Start Date:* April 1, 2024.

#### I. Funding Opportunity Description

*Statutory Authority*

The Indian Health Service (IHS), Office of Clinical and Preventive Services, Division of Behavioral Health (DBH) is accepting applications for grants for the Community Opioid Intervention Prevention Program (COIPP). This program is authorized under the Snyder Act, 25 U.S.C. 13, and the Transfer Act, 42 U.S.C. 2001(a). Funding for this program is provided in the Consolidated Appropriations Act, 2023, Public Law 117–328, 136 Stat. 4459, 4808 (2022). The Assistance Listings section of *SAM.gov* (*https://sam.gov/content/home*) describes this program under 93.654.

*Background*

The initial opioid prevention program, called the Community Opioid Intervention Pilot Project, was first established in Fiscal Year (FY) 2019, pursuant to Congressional instruction to better combat the opioid epidemic. The goal was to create a pilot program to address the opioid epidemic in Indian Country and award grants that supported the development, documentation, and sharing of locally designed and culturally appropriate prevention, treatment, recovery, and aftercare services for opioid use disorders in the American Indian and Alaska Native (AI/AN) communities. Evidence-based activities are available for reference at *https://www.ihs.gov/asap/coipp/.* A total of 35 grants were awarded to Tribal and Urban Indian communities in the pilot phase. Based on evaluation results from the pilot project, this funding opportunity will continue to provide grant support to Tribal and Urban Indian communities to continue efforts to combat the opioid epidemic and develop strategies that align with the Department of Health and Human Services Overdose Prevention Strategy.

The Centers for Disease Control and Prevention (CDC) reported that the AI/AN population had the highest drug overdose death rates in both 2020 and 2021, at rates of 42.5 and 56.6 deaths per 100,000 persons, respectively. The AI/AN population also experienced a 33 percent increase in drug overdose deaths from 2020 through 2021. Overdose deaths among AI/AN have continued to increase over the last 20 years. The CDC reported from 2019 to 2020, overdose death rates increased 39 percent for the non-Hispanic AI/AN population and drug overdose death rates were highest for AI/AN people compared to other racial and ethnic groups.