CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210563Orig1s000
210563Orig2s000

CLINICAL REVIEW(S)

CLINICAL REVIEW MEMORANDUM

DATE: February 13, 2017

TO: NDA 210563
Ibrutinib Tablets

FROM: Margret Merino, MD
Clinical Reviewer, DHP/OHOP/CDER

SUBJECT: Financial Disclosure Review

The Applicant submitted financial disclosure information from investigators and sub-investigators participating in trials 54179060CLL1018, Ibrutinib 54179060CLL1019, Ibrutinib 54179060CLL1021 and Ibrutinib 54179060CLL1022 indicating that none of the investigators reported disclosable financial interests or arrangements at any time during the trials.

Was a list of clinical investigators provided:	Yes X	No ☐ (Request list from Applicant)
Total number of investigators identified: 15 Investigators/Sub-investigators and 15 Trial nurses/pharmacists		
Number of investigators who are Sponsor employees (including both full-time and part-time employees): 2		
Number of investigators with disclosable financial interests/arrangements (Form FDA 3455): 0		
If there are investigators with disclosable financial interests/arrangements, identify the number of investigators with interests/arrangements in each category (as defined in 21 CFR 54.2(a), (b), (c) and (f)): Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0 Significant payments of other sorts: 0 Proprietary interest in the product tested held by investigator: 0 Significant equity interest held by investigator in Sponsor of covered study: 0		
Is an attachment provided with details of the disclosable financial interests/arrangements: N/A	Yes ☐	No ☐ (Request details from Applicant)
Is a description of the steps taken to minimize potential bias provided:	Yes ☒	No ☐ (Request information from Applicant)

Number of investigators with certification of due diligence (Form FDA 3454, box 3) 0		
Is an attachment provided with the reason:	Yes ☒	No ☐ (Request explanation from Applicant)

In addition to self-disclosure by the investigators, the sponsor assessed any royalty payments to investigators not related to study conduct who were listed as suppliers in the sponsor commercial payment system. The sponsor reported that none of the investigators who participated in the clinical studies appeared on the royalties schedule for the sponsor.

Reviewer Comment: There were no identified financial conflicts of interests for this application.

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

/s/

MARGRET E MERINO
02/13/2018

TANYA M WROBLEWSKI
02/13/2018

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	NDA 210563
Priority or Standard	Priority
Submit Date(s)	September 12, 2017
Received Date(s)	September 12, 2017
PDUFA Goal Date	February 28, 2018
Division / Office	DHP/OHOP
Reviewer Name(s)	Margret Merino, MD
Clinical Team Leader	Tanya Wroblewski, MD
Review Completion Date	1/16/2017
Established Name	Ibrutinib
Trade Name	Imbruvica®
Therapeutic Class	Bruton Tyrosine kinase inhibitor
Applicant	Pharmacyclics, LLC.
Formulation(s)	Tablets 140mg, 280mg, 420mg and 560mg, for oral use
Dosing Regimen	Provides new tablet formulations
Indication(s)	No new indications, provides new dosage formulation -Mantle cell lymphoma (MCL) -Marginal zone lymphoma (MZL)who require systemic therapy and have received at least one prior anti-CD20 based therapy -Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) -CLL/SLL with 17p deletion -Waldenström's macroglobulinemia (WM) -Chronic Graft vs. Host disease (cGVHD) after failure of one or more lines of systemic therapy
Intended Population(s)	No change to intended population Patients ≥ 18 years of age

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.