CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210563Orig1s000
210563Orig2s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

Date: February 13, 2018
From: Shwu-Luan Lee, PhD
Nonclinical Reviewer
Division of Hematology Oncology Toxicology (DHOT)
for Division of Hematology Products (DHP)
Through: Christopher M. Sheth, PhD
Nonclinical Supervisor
To: NDA 210563 ibrutinib
Re: Nonclinical Review

Ibrutinib is a kinase inhibitor indicated for the treatment of adult patients with Mantle cell lymphoma (MCL), Chronic lymphocytic leukemia (CLL), Small lymphocytic lymphoma (SLL), CLL/SLL with 17p deletion, Waldenström's macroglobulinemia (WM), and Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy, and Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. NDA 210563 is a Type-3 NDA for a tablet dosage form of the approved active ingredient ibrutinib. A capsule dosage form of ibrutinib (NDA 205552) is commercially available in the US under the trade name Imbruvica®. The nonclinical review is complete under NDA 205552. Refer to the documented review in DARRTS (NDA 205552 eCTD005) for additional details. There are no nonclinical issues that would prevent approval of this application.

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/s/

SHWU LUAN LEE
02/13/2018

CHRISTOPHER M SHETH
02/13/2018