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RESEARCH**

APPLICATION NUMBER:

205552Orig2s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA
Application Number 205552 Original-2
Priority or Standard Priority

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Reviewer Name Nicole Verdun, MD
Review Completion Date 10 February 2014

Established Name Ibrutinib
Trade Name Imbruvica
Therapeutic Class Kinase Inhibitor
Applicant Pharmacyclics, Inc.

Formulation(s) Tablet, 140 mg
Dosing Regimen 420 mg once daily
Indication(s) Patients with CLL who have
received at least one prior
therapy.
Intended Population(s) \geq 18 years of age

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