CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206073Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

BIOPHARMACEUTICS REVIEW ADDENDUM Office of New Drug Quality Assessment			
Application No.:	NDA 206-073	**Reviewer:** Kareen Riviere, Ph.D.	
Submission Date(s):	1/30/14; 6/3/14		
Division:	DMEP	**Secondary Signature:** Tapash Ghosh, Ph.D.	
Applicant:	Boehringer Ingelheim Pharmaceuticals, Inc.	**Supervisor:** Paul Seo, Ph.D.	
Trade Name:	Glyxambi	**Date Assigned:**	1/30/14
Generic Name:	empagliflozin/linagliptin fixed-dose combination tablets	**Date of Review:**	10/15/14
Indication:	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	**Type of Submission:** 505(b)(1) New Drug Application	
Formulation/strengths:	IR Tablet; 10 mg/5 mg and 25 mg/5mg		
Route of Administration:	Oral		

In the Biopharmaceutics review dated September 16, 2014, Dr. Kareen Riviere stated that Glyxambi (empagliflozin/linagliptin) 10 mg/5 mg and 25 mg/5mg immediate release tablets are recommended for approval from a Biopharmaceutics standpoint pending the OSI inspection results for the pivotal BE Study 1275.3. In the OSI inspection report for Study 1275.3 dated October 3, 2014, Drs. Seongeun (Julia) Cho and Sripal R. Mada stated:

> *Based on the inspectional outcomes, these reviewers conclude that the clinical and analytical portions of the Study 1275.003 are acceptable for further Agency review.*

Thus, NDA 206-073 for Glyxambi (empagliflozin/linagliptin) 10 mg/5 mg and 25 mg/5mg immediate release tablets is recommended for approval from the Biopharmaceutics perspective.

Kareen Riviere, Ph.D.
Biopharmaceutics Reviewer
Office of New Drug Quality Assessment

Tapash Ghosh, Ph.D.
Biopharmaceutics Team Leader
Office of New Drug Quality Assessment

cc: Dr. Paul Seo

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

/s/

KAREEN RIVIERE
10/15/2014

TAPASH K GHOSH
10/15/2014

OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA:	206073
Submission Date(s):	January 30, 2014
Brand Name	Glyxambi
Generic Name	Empagliflozin / Linagliptin FDC
OCP Division	Clinical Pharmacology -2
OND division	Metabolism and Endocrinology Products
Sponsor	Boehringer Ingelheim Pharmaceuticals, Inc.
Submission Type; Code	NDA 505(b)(1); Standard
Formulation; Strength(s)	Tablets: • 10 mg empagliflozin/5 mg linagliptin • 25 mg empagliflozin/5 mg linagliptin
Proposed Indication	• Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when both empagliflozin and linagliptin is appropriate.
Dosage & Administration	• The recommended starting dose of Glyxambi is 10 mg empagliflozin/5 mg linagliptin once daily. • Dose can be increased to 25 mg empagliflozin/5 mg linagliptin once daily in patients who require additional glycemic control. • Glyxambi can be taken with or without food. • Do not initiate Glyxambi if eGFR is below 45 mL/min/1.73 m^2
Clinical Pharmacology Reviewer	Suryanarayana Sista, PhD
Clinical Pharmacology Team Leader (Acting)	Manoj Khurana, PhD

TABLE OF CONTENTS

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.