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APPLICATION NUMBER:

206073Orig1s000

SUMMARY REVIEW

NDA-206073
Sponsor: Boehringer Ingelheim
SD-1, eCTD-0000
Received: January 29, 2014
Primary Safety Review/CDTL
Reviewer: William H. Chong

CLINICAL REVIEW/CROSS-DISCIPLINE TEAM LEADER REVIEW

Application NDA-206073
Supporting Document Number SD-1

Submission Receipt Date January 29, 2014
PDUFA Goal Date January 30, 2015
Division Division of Metabolism and Endocrinology
Products

Reviewer William H. Chong
Review Completion Date January 29, 2015

Generic name Empagliflozin/Linagliptin
Trade name GLYXAMBI
Therapeutic class Fixed dose combination of a sodium dependent
glucose cotransporter-2 inhibitor and a
dipeptidyl peptidase-4 inhibitor
Applicant Boehringer Ingelheim
Priority designation Standard

Formulation Tablet
Dosing regimen Empagliflozin 10 mg/Linagliptin 5 mg
Empagliflozin 25 mg/Linagliptin 5 mg
Indication Type 2 diabetes mellitus
Intended population Adults with type 2 diabetes mellitus

Related INDs/NDAs IND-108388 (Empagliflozin/Linagliptin);
NDA-201280 (Linagliptin); NDA-204629
(Empagliflozin)

Division Director Jean-Marc Guettier
Statistical Reviewer Jennifer Clark
Clinical Pharmacology Reviewer Suryanarayana Sista
Pharmacology/Toxicology Reviewer David Carlson
Chemistry, Manufacturing and Controls Joseph Leginus and Kareen Riviere
Project Manager Callie Cappel-Lynch

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