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APPLICATION NUMBER:

22-044

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA
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Reviewer Name Ilan Irony
Through: Mary Parks
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Established Name: Sitagliptin / metformin fixed-dose combination
(Proposed) Trade Name Janumet
Therapeutic Class: Dipeptidyl peptidase IV inhibitor / biguanide
Applicant Merck and Company, Inc.

Priority Designation S

Formulation Oral Tablet
Dosing Regimen 50 mg / 500 mg and 50 mg /1000 mg twice daily
Indication Improve glycemic control
Intended Population Adult patients with Type 2 diabetes mellitus

Table of Contents

1 EXECUTIVE SUMMARY.....5

1.1 RECOMMENDATION ON REGULATORY ACTION5

1.2 RECOMMENDATION ON POSTMARKETING ACTIONS6

1.2.1 Risk Management Activity6

1.2.2 Required Phase 4 Commitments6

1.2.3 Other Phase 4 Requests.....6

1.2.4 Recommended Trade Name.....6

1.3 SUMMARY OF CLINICAL FINDINGS6

1.3.1 Brief Overview of Clinical Program7

1.3.2 Efficacy.....7

1.3.3 Safety10

1.3.4 Dosing Regimen and Administration.....10

1.3.5 Drug-Drug Interactions.....11

1.3.6 Special Populations.....12

2 INTRODUCTION AND BACKGROUND.....13

2.1 PRODUCT INFORMATION13

2.1.1 Product description13

2.1.2 Established name and proposed trade name14

2.1.3 Chemical class14

2.1.4 Pharmacologic class.....14

2.1.5 Proposed indications, dosing regimens and age groups.....15

2.2 CURRENTLY AVAILABLE TREATMENT FOR INDICATIONS15

2.3 AVAILABILITY OF PROPOSED ACTIVE INGREDIENT IN THE UNITED STATES16

2.4 IMPORTANT ISSUES WITH PHARMACOLOGICALLY RELATED PRODUCTS.....16

2.5 PRESUBMISSION REGULATORY ACTIVITY16

2.6 OTHER RELEVANT BACKGROUND INFORMATION.....17

3 SIGNIFICANT FINDINGS FROM OTHER REVIEW DISCIPLINES19

3.1 CMC (AND PRODUCT MICROBIOLOGY, IF APPLICABLE)19

3.2 ANIMAL PHARMACOLOGY/TOXICOLOGY20

4 DATA SOURCES, REVIEW STRATEGY, AND DATA INTEGRITY.....22

4.1 SOURCES OF CLINICAL DATA22

4.2 TABLES OF CLINICAL STUDIES22

4.3 REVIEW STRATEGY26

4.4 DATA QUALITY AND INTEGRITY26

4.5 COMPLIANCE WITH GOOD CLINICAL PRACTICES.....27

4.6 FINANCIAL DISCLOSURES.....27

5 CLINICAL PHARMACOLOGY28

5.1 PHARMACOKINETICS29

5.2 PHARMACODYNAMICS.....34

5.3 EXPOSURE-RESPONSE RELATIONSHIPS36

6 INTEGRATED REVIEW OF EFFICACY37

6.1 INDICATION.....37

6.1.1 Methods37

6.1.2 General Discussion of Endpoints.....38

6.1.3 Study Design.....38

6.1.4 Efficacy Findings.....41

Clinical Review
 Ilan Irony, M.D.
 NDA 22044, Submission 000
 Janumet™ (Sitagliptin / metformin fixed-dose combination)

6.1.5	Clinical Microbiology	45
6.1.6	Efficacy Conclusions	46
7	INTEGRATED REVIEW OF SAFETY	46
7.1	METHODS AND FINDINGS	46
7.1.1	Deaths	46
7.1.2	Other Serious Adverse Events	48
7.1.3	Dropouts and Other Significant Adverse Events	52
7.1.4	Other Search Strategies	61
7.1.5	Common Adverse Events	61
7.1.6	Less Common Adverse Events	66
7.1.7	Laboratory Findings	66
7.1.8	Vital Signs	75
7.1.9	Electrocardiograms (ECGs)	78
7.1.10	Immunogenicity	82
7.1.11	Human Carcinogenicity	83
7.1.12	Special Safety Studies	83
7.1.13	Withdrawal Phenomena and/or Abuse Potential	83
7.1.14	Human Reproduction and Pregnancy Data	84
7.1.15	Assessment of Effect on Growth	84
7.1.16	Overdose Experience	84
7.1.17	Postmarketing Experience	85
7.2	ADEQUACY OF PATIENT EXPOSURE AND SAFETY ASSESSMENTS	85
7.2.1	Description of Primary Clinical Data Sources (Populations Exposed and Extent of Exposure) Used to Evaluate Safety	85
7.2.2	Description of Secondary Clinical Data Sources Used to Evaluate Safety	89
7.2.3	Adequacy of Overall Clinical Experience	89
7.2.4	Adequacy of Special Animal and/or In Vitro Testing	89
7.2.5	Adequacy of Routine Clinical Testing	90
7.2.6	Adequacy of Metabolic, Clearance, and Interaction Workup	90
7.2.7	Adequacy of Evaluation for Potential Adverse Events for Any New Drug and Particularly for Drugs in the Class Represented by the New Drug; Recommendations for Further Study	90
7.2.8	Assessment of Quality and Completeness of Data	90
7.2.9	Additional Submissions, Including Safety Update	90
7.3	SUMMARY OF SELECTED DRUG-RELATED ADVERSE EVENTS, IMPORTANT LIMITATIONS OF DATA, AND CONCLUSIONS	91
7.4	GENERAL METHODOLOGY	92
7.4.1	Pooling Data Across Studies to Estimate and Compare Incidence	92
7.4.2	Explorations for Predictive Factors	92
7.4.3	Causality Determination	94
8	ADDITIONAL CLINICAL ISSUES	94
8.1	DOSING REGIMEN AND ADMINISTRATION	94
8.2	DRUG-DRUG INTERACTIONS	94
8.3	SPECIAL POPULATIONS	95
8.4	PEDIATRICS	96
8.5	ADVISORY COMMITTEE MEETING	96
8.6	LITERATURE REVIEW	97
8.7	POSTMARKETING RISK MANAGEMENT PLAN	97
8.8	OTHER RELEVANT MATERIALS	98
9	OVERALL ASSESSMENT	98
9.1	CONCLUSIONS	98
9.2	RECOMMENDATION ON REGULATORY ACTION	99
9.3	RECOMMENDATION ON POSTMARKETING ACTIONS	99

Clinical Review
Ilan Irony, M.D.
NDA 22044, Submission 000
Janumet™ (Sitagliptin / metformin fixed-dose combination)

9.3.1	Risk Management Activity	99
9.3.2	Required Phase 4 Commitments	99
9.3.3	Other Phase 4 Requests	100
9.4	LABELING REVIEW	100
9.5	COMMENTS TO APPLICANT	100
10	APPENDICES	101
10.1	REVIEW OF INDIVIDUAL STUDY REPORTS	101
10.2	LINE-BY-LINE LABELING REVIEW	102
	REFERENCES	105

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