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STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA Serial Number: 22-406

Drug Name: XARELTO (rivaroxaban) Film-coated 10 mg tablet for oral intake

Indication(s): Prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery (10 mg orally, once daily)

Applicant: Johnson and Johnson Pharmaceutical Research and Development, LLC

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Table of Contents

LIST OF TABLES	3
LIST OF FIGURES	4
1. EXECUTIVE SUMMARY	5
2. INTRODUCTION.....	7
2.1 OVERVIEW	7
2.2 DATA SOURCES	11
3. STATISTICAL EVALUATION.....	11
3.1 DATA AND ANALYSIS QUALITY	11
3.2 EVALUATION OF EFFICACY.....	12
3.3 EVALUATION OF SAFETY	12
3.3.1 <i>Study Design and Endpoints</i>	12
3.3.2 <i>Study Populations and Extent of Exposure</i>	14
3.3.3 <i>Demographic and Baseline Characteristics</i>	18
3.3.4 <i>Endpoints and Statistical Methodologies</i>	19
3.3.5 <i>Applicant’s Results and Statistical Safety Reviewer’s Findings and Comments</i>	21
4. FINDINGS IN SPECIAL/SUBGROUP POPULATIONS	32
5. SUMMARY AND CONCLUSIONS.....	33
5.1 STATISTICAL ISSUES AND COLLECTIVE EVIDENCE	33
5.2 CONCLUSIONS AND RECOMMENDATIONS	35
APPENDIX I: HEPATIC ADVERSE EVENTS BY MEDDRA PREFERRED TERM.....	37
A. ROCKET AND J-ROCKET	37
B. EINSTEIN DVT/PE	40
C. EINSTEIN EXTENSION.....	42
SIGNATURES/DISTRIBUTION LIST.....	43

LIST OF TABLES

Table 1: Summary of Laboratory Findings.....	6
Table 2: Summary of Clinical Studies	10
Table 3: Study Populations for Rocket, J-Rocket and Einstein Studies	15
Table 4: Subject Years of Exposure for Rocket, J-Rocket and Einstein Studies.....	15
Table 5: Number of Subjects in the Safety Population in Record 1-4 Studies	16
Table 6: Duration of Treatment of Active Study Medication by Study in Record 1-4 Studies....	16
Table 7: ALT Measurements by Study Week in Rocket, J-Rocket and Pooled.....	17
Table 8: TBL Data Measurements by Study Week in Rocket, J-Rocket and Pooled.....	17
Table 9: Study Medication Completion/Withdrawal Information During the Double-Blind Period (Rocket Study)	18
Table 10: Demographic and Baseline Characteristics (All Randomized Subjects).....	19
Table 11: ALT (SGPT) Post Baseline Data*	22
Table 12: Total Bilirubin (based on central laboratory) Post-Baseline Data.....	23
Table 13: Incidence of Prespecified Laboratory Abnormalities with Hazard Ratios (Combined ALT>3xULN and TBL>2xULN) (Based on Central and Local laboratory assessments) Rocket and J-Rocket: Safety Analysis Set	25
Table 14: Total Bilirubin Post-Baseline Data Corresponding to ALT>3xULN.....	27
Table 15: ALT>3x ULN Occurrence by Study Window.....	28
Table 16: TBL>2x ULN Occurrence by Study Window	28
Table 17: ALT>3x, TBL>2x ULN (Hy's Law Cases) Occurrence by Study Window	29
Table 18: Post-baseline Hepatic-Related AEs in Rocket and J-Rocket Studies*	30
Table 19: Hepatic adverse events among identified Hy's Law Cases.....	31
Table 20: Summary of Post-baseline Adverse Events in Einstein DVT and PE Studies*	31
Table 21: Analysis of ALT>3x ULN by Gender and Race in the Rocket Study	32
Table 22: Subgroups for Hy's Law Cases in the Rocket Study	33

LIST OF FIGURES

Figure 1: Scatter Plot of Baseline and Postbaseline Maximum ALT Levels with Maximum Total Bilirubin Levels (Based on Central and Local laboratory assessment) Rocket and J-Rocket: Safety Analysis Set 24

Figure 2: Hazard Ratios and 95% CIs for the Time from the First Study Drug Administration to the First Post-baseline Occurrence of Hy's Law Cases Either on the Same Day or Within 30 Days (Based on Central and Local laboratory assessments)..... 26

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