

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
January 16, 2014

AGENDA

The committee will discuss supplemental new drug application (sNDA) 202439/S-002 rivaroxaban, tradename XARELTO 2.5 mg tablets, submitted by Janssen Pharmaceuticals, Inc. for the proposed indication to reduce the risk of thrombotic cardiovascular events in patients in the first 90 days after suffering acute coronary syndrome (ACS) [ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA)].

8:00 a.m.	Call to Order Introduction of Committee	Philip Sager, MD Acting Chairperson, CRDAC
8:05 a.m.	Conflict of Interest Statement	Kristina A. Toliver, PharmD Designated Federal Officer, CRDAC
8:10 a.m.	Opening Remarks	Norman Stockbridge, MD, PhD Director Division of Cardiovascular and Renal Products (DCaRP) Office of Drug Evaluation I (ODEI) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	<u>Applicant Presentations</u>	<u>Janssen Pharmaceuticals</u>
	Introduction	Paul Burton, MD, PhD Vice President, Clinical Development, Janssen
	ATLAS ACS Program Overview and Results	C. Michael Gibson, MD, MS Coordinating Principal Investigator ATLAS ACS 2 TIMI 51 Professor of Medicine, Harvard Medical School
		Roderick A. Little, PhD Richard D. Remington Distinguished University Professor of Biostatistics, University of Michigan
		Paul Burton, MD, PhD
	Evidence of Effectiveness	Jay Siegel, MD Head of Scientific Strategy and Policy, Johnson & Johnson
	Balancing Benefit and Risk	Marvin A. Konstam, MD Chief Physician Executive, The CardioVascular Center at Tufts Medical Center, Professor of Medicine at Tufts University School of Medicine

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AGENDA (cont.)

9:50 a.m. Clarifying Questions to the Presenters

10:20 a.m. **BREAK**

10:35 a.m. **FDA Presentations**

Rivaroxaban for ACS:
sNDA 202439/S-002

Stephen Grant, MD
Clinical Reviewer
DCaRP, ODEI, OND, CDER, FDA

Thomas Marciniak, MD
Clinical Reviewer
DCaRP, ODEI, OND, CDER, FDA

11:35 a.m. Clarifying Questions to the Presenters

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee and Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee and Committee Discussion (cont.)

5:00 p.m. **ADJOURNMENT**