

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 15, 2014

AGENDA

The committee will discuss New Drug Application 204886, vorapaxar tablets, submitted by Merck Sharp & Dohme Corp. for the proposed indication of reduction of atherothrombotic events in patients with a history of myocardial infarction (MI). The applicant also proposes that vorapaxar has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR).

8:00 a.m.	Call to Order Introduction of Committee	Philip Sager, MD, FACC, FAHA, FHRS 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>Sponsor Presentations</u>	<u>Merck Sharp & Dohme Corp.</u>
	Introduction to Vorapaxar	Chitkala Kalidas, PhD Director, Merck Regulatory Affairs
	Clinical Program Overview	John Strony, MD Executive Director, Merck Clinical Research
	Vorapaxar Pivotal TRA 2°P – TIMI 50 Results in the Overall Population	David Morrow, MD, MPH Senior Investigator, TIMI Study Group Brigham and Women's Hospital
	TRA 2°P – TIMI 50 Results in Proposed Label Population	Daniel Bloomfield, MD Vice President, Clinical Research Merck Research Laboratories
	Vorapaxar Benefit-Risk	Eugene Braunwald, MD Founding Chairman, TIMI Study Group Brigham and Women's Hospital

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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 Presentation**

Clinical & Statistical Issues

Martin Rose, MD, JD

Clinical Reviewer

DCaRP, ODEI, OND, CDER, FDA

11:15 a.m. Clarifying Questions to the Presenter

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**