The committee will discuss supplemental new drug application 202057/S-035, for VASCEPA (icosapent ethyl) capsules for oral administration, sponsored by Amarin Pharma Inc., for the following proposed indication: to reduce the risk of cardiovascular events, as an adjunct to statin therapy in adult patients with elevated triglycerides levels (135 mg/dL or greater) and other risk factors for cardiovascular disease, based on the results of a clinical study entitled “A Study of AMR101 to Evaluate Its Ability to Reduce Cardiovascular Events in High Risk Patients With Hypertriglyceridemia and on Statin. The Primary Objective is to Evaluate the Effect of 4 g/Day AMR101 for Preventing the Occurrence of a First Major Cardiovascular Event. (REDUCE-IT)” (available at: https://clinicaltrials.gov/ct2/show/NCT01492361).

8:00 a.m. Call to Order and Introduction of Committee

Kenneth D. Burman, MD
Chairperson, EMDAC

8:05 a.m. Conflict of Interest Statement

Jay Fajiculay, PharmD
Designated Federal Officer (Acting), EMDAC

8:10 a.m. FDA Introductory Remarks

John Sharretts, MD
Deputy Director (Acting)
Division of Metabolism and Endocrinology Products (DMEP)
Office of Drug Evaluation II (ODE-II)
Office of New Drugs (OND), CDER, FDA

8:20 a.m. APPLICANT PRESENTATIONS

Amarin Pharma Inc.

Introduction

Rebecca Juliano, PhD
Senior Vice President
Clinical Research and Development
Amarin Pharma Inc.

Medical Need

Michael Miller, MD
Professor of Cardiovascular Medicine, Epidemiology & Public Health
Director, Center for Preventative Cardiology
University of Maryland School of Medicine

REDUCE-IT Clinical Efficacy and Safety Data

Deepak L. Bhatt, MD, MPH
Executive Director of Interventional Cardiovascular Programs, Professor
Brigham and Women’s Hospital
Harvard Medical School

Clinical Perspectives

Ann Marie Navar, MD, PhD
Assistant Professor of Cardiology
Duke University School of Medicine
Duke Clinical Research Institute
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
November 14, 2019

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Closing Remarks                                                    Rebecca Juliano, PhD
9:50 a.m.  Clarifying Questions to Applicant
10:05 a.m.  BREAK
10:20 a.m.  FDA PRESENTATIONS

Introduction and Clinical Review                                  Iffat Nasrin Chowdhury, MD
Medical Officer
DMEP, ODE-II, OND, CDER, FDA

Statistical Review of Efficacy                                    Roberto Crackel, PhD
Statistical Reviewer
Division of Biometrics II
Office of Biostatistics
Office of Translational Sciences (OTS), CDER FDA

Clinical Pharmacology Review                                      Yunzhao Ren, MD, PhD
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology II
Office of Clinical Pharmacology, OTS, CDER, FDA

Additional Statistical Analysis and Conclusions                  Roberto Crackel, PhD

Clinical Review of Safety                                          Iffat Nasrin Chowdhury, MD

11:50 a.m.  Clarifying Questions to FDA
12:05 p.m.  LUNCH
1:05 p.m.   OPEN PUBLIC HEARING
2:15 p.m.   Questions to the Committee/Committee Discussion
3:45 p.m.   BREAK
4:00 p.m.   Questions to the Committee/Committee Discussion
5:00 p.m.   ADJOURNMENT