The committee will discuss supplemental new drug application (sNDA) 205832 for nintedanib capsules (drug name OFEV), sponsored by Boehringer Ingelheim, for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD). The focus of the discussion will be whether the application provides substantial evidence of efficacy for the proposed indication.

8:30 a.m. Call to Order and Introduction of Committee

Daniel Solomon, MD
Chairperson, AAC

8:35 a.m. Conflict of Interest Statement

Yinghua S. Wang, PharmD, MPH, RAC
Designated Federal Officer, AAC

8:40 a.m. FDA Opening Remarks

Rachel Glaser, MD
Clinical Team Leader
Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Office of Drug Evaluation II (ODE-II)
Office of New Drugs (OND), CDER, FDA

8:50 a.m. APPLICANT PRESENTATIONS

Boehringer Ingelheim

Introduction

Kay Teztlaff, MD
Medical Head
Therapeutic Area Respiratory Diseases
Boehringer Ingelheim

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Background and Unmet Medical Need

James R. Seibold, MD
Principal Member
Scleroderma Research Consultants

Clinical Development Rationale for SSc-ILD

Susanne Stowasser, MD
Associate Head Medicine
Therapeutic Area Respiratory Diseases
Boehringer Ingelheim

Efficacy of Nintedanib for SSc-ILD

Emmanuelle Clerisme-Beaty, MD
Senior Clinical Program Leader
Therapeutic Area Respiratory Diseases
Boehringer Ingelheim

Safety of Nintedanib for SSc-ILD

Veronika M. Kohlbrenner, MD
Director
Global Pharmacovigilance
Boehringer Ingelheim
AGENDA

APPLICANT PRESENTATIONS (cont.)

Benefit/Risk of Nintedanib for SSc-ILD  Kay Teztlaff, MD
Clinical Prospective  Kevin K. Brown, MD
Professor of Medicine
National Jewish Health

10:20 a.m.  Clarifying Questions
10:35 a.m.  BREAK
10:50 a.m.  FDA PRESENTATIONS

Overview of Clinical Program  Nadia Habal, MD
Medical Officer
DPARP, ODE-II, OND, CDER, FDA

Statistical Review of Efficacy  Yu Wang, PhD
Statistical Reviewer
Division of Biometrics II, Office of Biostatistics
Office of Translational Sciences, CDER, FDA

Clinical Review of Safety and Benefit-Risk Assessment  Nadia Habal, MD

11:50 am  Clarifying Questions
12:00 p.m.  LUNCH
1:00 p.m.  Open Public Hearing
2:00 p.m.  Charge to the Committee  Rachel Glaser, MD
2:15 p.m.  Questions to the Committee/Committee Discussion
3:15 p.m.  BREAK
3:30 p.m.  Questions to the Committee/Committee Discussion
5:00 p.m.  ADJOURNMENT