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

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 25, 2019

DRAFT AGENDA

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 Introductory 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

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	SPONSOR 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**	