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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
August 31, 2020

DRAFT AGENDA

The committee will discuss supplemental new drug application 209482/S-008, for TRELEGY ELLIPTA, a fixed-dose combination (fluticasone furoate, umeclidinium, and vilanterol inhalation powder oral inhalation), submitted by GlaxoSmithKline, for the following proposed labeling claim: Reduction in all-cause mortality in patients with chronic obstructive pulmonary disease (COPD). The focus of the discussion will be on the efficacy data submitted to support the proposed labeling claim, including the results from the Informing the Pathway of COPD Treatment trial and the influence of inhaled corticosteroids withdrawal on the results.

10:00 a.m.	Call to Order and Introduction of Committee	**James Stoller, MD, MS** Acting Chairperson, PADAC
10:10 a.m.	Conflict of Interest Statement	**Philip Bautista, PharmD** Acting Designated Federal Officer, PADAC
10:15 a.m.	FDA Introductory Remarks	**Banu A. Karimi-Shah, MD** Deputy Director Division of Pulmonology, Allergy, and Critical Care, Office of Immunology and Inflammation Office of New Drugs, CDER, FDA
10:25 a.m.	**APPLICANT PRESENTATION**	**GlaxoSmithKline**
	Request to Amend the TRELEGY™ ELLIPTA® Label to Include Data on the Reduction in Risk of All-Cause Mortality in Patients with COPD	**C. Elaine Jones, PhD** Medicine Development Leader Trelegy COPD GlaxoSmithKline
10:45 a.m.	Clarifying Questions to the Applicant	
11:15 a.m.	**FDA PRESENTATION**	
	FDA Summary Presentation	**Banu A. Karimi-Shah, MD**
11:35 a.m.	Clarifying Questions to the FDA	
12:05 p.m.	**LUNCH**	
12:50 p.m.	Open Public Hearing	
1:50 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	**ADJOURNMENT**	

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