FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics VI (GREAT VI) Workshop on Celiac Disease

Virtual meeting
July 22, 2021

AGENDA

The goal of today's workshop is to discuss the overall approach to drug development in celiac disease that includes an assessment of both clinical symptoms and histology. The workshop will focus the discussion on the histologic endpoints to assess treatment benefit in patients with celiac disease; regulatory framework for pediatric drug development in celiac disease; and the role of gluten challenge in clinical trials to provide a forum for open discussion between stakeholders to facilitate drug development.

9:00 a.m. **Opening Remarks** *(5 min)*

Considerations for drug development in celiac disease in adults: FDA perspective *(15 min)*

9:20 a.m. **Session 1: Histologic assessment in the evaluation of the underlying disease and treatment benefit in celiac disease**

Approach to monitoring disease through histologic assessment in clinical practice *(15 min)*

Unique considerations for using histologic assessments to monitor disease in pediatric patients *(10 min)*

Histologic characteristics to define disease severity and remission: a pathologist's perspective *(10 min)*

9:55 a.m.	Break	*(10 min)*
10:05 a.m.	Panel discussion and Q & A*	*(40 min)*
10:45 a.m.	**Session 2: Pediatric celiac disease**	
	Extrapolation of efficacy: Regulatory considerations	*(10 min)*
	Pediatric patient's perspective on living with celiac disease and goals of treatment	*(10 min)*
	Clinical manifestations, natural history, and unmet needs of pediatric celiac disease	*(15 min)*
	FDA perspective: Defining clinical benefit in pediatric clinical trials for celiac disease	*(15 min)*
11:35 a.m.	Break	*(15 min)*
11:50 a.m.	Panel discussion and Q & A*	*(40 min)*
12:30 a.m.	**Lunch**	(*60 min)*
1:30 p.m.	**Session 3: Gluten challenge in clinical trials**	
	FDA introductory remarks for the session	*(5 min)*
	Gluten challenges and unintentional gluten exposure in clinical practice	*(10 min)*
	Dose and duration of gluten exposure that elicits clinical signs/symptoms and changes in histology in patients	*(10 min)*
	Role of gluten challenge in clinical trials: Industry perspective	*(10 min)*
2:05 p.m.	Break	*(15 min)*

2:20 p.m.	Panel discussion and Q & A*	*(45 min)*
3:05 p.m.	**Closing Remarks**	*(5 min)*
3:10 p.m.	**Adjournment**	

***To facilitate discussion, please submit all questions for the panel prior to the session break**