

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 13, 2019

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 761143, teprotumumab solution for intravenous use, submitted by Horizon Pharma Ireland, Ltd., proposed for the treatment of active thyroid eye disease.

8:00 a.m.	Call to Order and Introduction of Committee	James Chodosh, MD Chairperson, DODAC
8:05 a.m.	Conflict of Interest Statement	Jay R. Fajiculay, PharmD Designated Federal Officer (Acting), DODAC
8:10 a.m.	FDA Opening Remarks	Wiley A. Chambers, MD Deputy Director Division of Transplant and Ophthalmology Products Office of New Drugs, CDER, FDA
8:20 a.m.	APPLICANT PRESENTATIONS	Horizon Pharma Ireland, Ltd.
	Introduction	Timothy P. Walbert Chairman, President and Chief Executive Officer Horizon Therapeutics
	Unmet Medical Need	Raymond S. Douglas, MD, PhD Director of Orbital and Thyroid Eye Disease Program Cedars-Sinai Medical Center
	Teprotumumab Mechanism and Program Overview	Shao-Lee Lin, MD, PhD Executive Vice President, Head of Research and Development, Chief Scientific Officer Horizon Therapeutics
	Efficacy and Safety	Elizabeth H.Z. Thompson, PhD Vice President, Clinical Development, Rare Disease Horizon Therapeutics
	Clinical Perspective	Raymond S. Douglas, MD, PhD
9:50 a.m.	Clarifying Questions to the Applicant	
10:05 a.m.	BREAK	
10:20 a.m.	Clarifying Questions to the Applicant (continued)	

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DRAFT AGENDA (cont.)

10:35 a.m. **FDA PRESENTATION**

FDA Clinical Review of
Teprotumumab

Wiley A. Chambers, MD

11:10 a.m. Clarifying Questions to FDA

11:30 a.m. **LUNCH**

12:30 p.m. **OPEN PUBLIC HEARING**

1:30 p.m. Questions to the Committee/ Committee Discussion

2:30 p.m. **BREAK**

2:45 pm. Questions to the Committee/ Committee Discussion (cont.)

4:00 p.m. **ADJOURNMENT**