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

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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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 p.m.	Questions to the Committee/ Committee Discussion (cont.)	
4:00 p.m.	**ADJOURNMENT**	