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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
June 28, 2023

AGENDA

The committee will discuss new drug application (NDA) 215559, for palovarotene capsules, submitted by Ipsen Biopharmaceuticals, Inc. The proposed indication is the prevention of heterotopic ossification in adults and children (females aged 8 years and above and males 10 years and above) with fibrodysplasia ossificans progressive.

9:30 a.m.	Call to Order	**Cecilia Low Wang, MD** Chairperson, EMDAC
9:40 a.m.	Introduction of Committee and Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
9:50 a.m.	FDA Opening Remarks	**Theresa Kehoe, MD** Director Division of General Endocrinology (DGE) Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
10:05 a.m.	**SPONSOR PRESENTATIONS**	**Ipsen Biopharmaceuticals, Inc.**
	Introduction	**Howard Mayer, MD** Executive Vice President, Head of Research and Development Ipsen Biopharmaceuticals, Inc.
	Unmet Need in Fibrodysplasia Ossificans Progressiva (FOP)	**Matthew Brown, MBBS, MD, FRACP, FAA** Professor of Medicine, King's College London Chief Scientific Officer, Genomics England
	Efficacy	**Rose Marino, MD** Vice President, Clinical Development Rare Disease Ipsen Biopharmaceuticals, Inc.
	Safety and Risk Management Activities	**Jennifer Schranz, MD** Senior Vice President, Global Head Rare Disease Ipsen Biopharmaceuticals, Inc.

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	Clinical Perspective	**Edward Hsiao, MD, PhD** Professor of Medicine Division of Endocrinology and Metabolism University of California, San Francisco
11:05 a.m.	Clarifying Questions for Sponsor	
11:25 a.m.	**BREAK**	
11:40 a.m.	**FDA PRESENTATIONS**	
	Overview of Clinical Studies	**Stephen Voss, MD** Clinical Reviewer DGE, OCHEN, OND, CDER, FDA
	Statistical Review	**Alexander Cambon, PhD** Statistical Reviewer Division of Biometrics II, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Overview of Safety	**Stephen Voss, MD**
12:40 p.m.	Clarifying Questions for FDA	
1:00 p.m.	**LUNCH**	
2:00 p.m.	**OPEN PUBLIC HEARING**	
3:00 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	**BREAK**	
4:10 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:30 p.m.	**ADJOURNMENT**	