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

Oncologic Drugs Advisory Committee (ODAC) Meeting
August 13, 2020

AGENDA

The committee will discuss biologics license application (BLA) 125706, for remestemcel-L (ex-vivo culture-expanded adult human mesenchymal stromal cells suspension for intravenous infusion), submitted by Mesoblast, Inc. The proposed indication (use) for this product is for the treatment of steroid-refractory acute graft-versus-host disease in pediatric patients. The morning session will discuss issues related to the characterization and critical quality attributes of remestemcel-L as they relate to clinical effectiveness. The afternoon session will discuss results from clinical trials included in BLA 125706.

Morning Session

8:00 a.m.	Call to Order and Introduction of Committee	**Philip C. Hoffman, MD** Chairperson, ODAC
	Conflict of Interest Statement	**Joyce Yu, PharmD** Acting Designated Federal Officer, ODAC
8:10 a.m.	FDA Opening Remarks	**Wilson Bryan, MD** Director Office of Tissues and Advanced Therapies (OTAT) Center for Biologics Evaluation and Research (CBER), FDA
8:15 a.m.	**GUEST SPEAKER PRESENTATION**	
	Cell Manufacture for Therapeutic Application	**Sally Temple, PhD** Scientific Director Neural Stem Cell Institute Rensselaer, New York
8:55 a.m.	**APPLICANT PRESENTATIONS**	**Mesoblast, Inc.**
	Introduction to Remestemcel-L	**Geraldine Storton, BSc, MMS, MBA** Head of Regulatory Affairs & Quality Management Mesoblast, Inc.
	Manufacturing Process	

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Pathophysiology of Acute Graft-versus-Host Disease (aGVHD)	**Silviu Itescu, MD** Chief Executive Officer Mesoblast, Inc.
	Mechanism of Action (MoA) of Remestemcel-L in aGVHD	
	Potency Assay and Relationship to Clinical Outcomes	
9:20 a.m.	**FDA PRESENTATION**	
	Product Characterization	**Steven Bauer, PhD** Branch Chief Cellular and Tissue Therapy Branch (CTTB) Division of Cellular & Gene Therapies (DCGT) OTAT, CBER, FDA
9:45 a.m.	Clarifying Questions to Presenters	
10:00 a.m.	**BREAK**	
10:10 a.m.	**OPEN PUBLIC HEARING**	
10:40 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	**LUNCH**	

Afternoon Session

1:00 p.m.	Call to Order and Introduction of Committee	**Philip C. Hoffman, MD** Chairperson, ODAC
	Conflict of Interest Statement	**Joyce Yu, PharmD** Acting Designated Federal Officer, ODAC

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AGENDA (cont.)

1:10 p.m.	FDA Opening Remarks	**Bindu George, MD** Branch Chief Clinical Hematology Branch (CHB) Division of Clinical Evaluation & Pharmacology/Toxicology (DCEPT) OTAT, CBER, FDA
1:15 p.m.	**APPLICANT PRESENTATIONS**	**Mesoblast, Inc.**
	Introduction to Remestemcel-L	**Geraldine Storton, BSc, MMS, MBA**
	Unmet Need in Steroid-Refractory Acute Graft-versus-Host Disease (SR-aGVHD)	**Joanne Kurtzberg, MD** Director, Marcus Center for Cellular Cures Director, Pediatric Blood and Marrow Transplant Program Director, Carolinas Cord Blood Bank Duke University School of Medicine
	Remestemcel-L Clinical Efficacy and Safety	**Fred Grossman, DO** Chief Medical Officer Mesoblast, Inc.
	Clinical Perspective	**Joanne Kurtzberg, MD**
2:00 p.m.	**FDA PRESENTATION**	
	Clinical Evidence	**Kristin Baird, MD** Clinical Reviewer CHB, DCEPT, OTAT, CBER, FDA
2:45 p.m.	Clarifying Questions to Presenters	
3:15 p.m.	**BREAK**	
3:30 p.m.	**OPEN PUBLIC HEARING**	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	