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

Medical Imaging Drugs Advisory Committee (MIDAC) Meeting

March 5, 2024

AGENDA

The Committee will discuss efficacy and safety data submitted in support of new drug application (NDA) 214511 for pegulicianine for injection, the optical imaging drug constituent of a drug/device combination product, submitted by Lumicell, Inc. The proposed indication for pegulicianine is for use in patients with breast cancer to assist in the detection of cancerous tissue within the lumpectomy cavity following removal of the primary specimen during lumpectomy surgery.

9:00 a.m.	Call to Order	**Henry Royal, MD** Chairperson, MIDAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Acting Designated Federal Officer, MIDAC
9:15 a.m.	FDA Introductory Remarks	**A. Alex Hofling, MD, PhD** Deputy Division Director Division of Imaging and Radiation Medicine (DIRM) Office of Specialty Medicine (OSM) Office of New Drugs (OND), CDER, FDA
9:35 a.m.	**APPLICANT PRESENTATIONS**	**Lumicell, Inc.**
	Introduction	**Jorge Ferrer, PhD** Chief Scientific Officer Lumicell, Inc.
	Unmet Need	**Kelly Hunt, MD, FACS, FSSO** Professor and Chair Department of Breast Surgical Oncology Division of Surgery MD Anderson Cancer Center President, Society of Surgical Oncologists
	Pivotal Study CL0007 Efficacy Results	**E. Shelley Hwang, MD, MPH** Mary and Deryl Hart Distinguished Professor of Surgery Vice Chair of Research Department of Surgery Leader, Breast Cancer Disease Group Duke University and Duke Cancer Institute

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APPLICANT PRESENTATIONS (CONT.)

	Safety	**Peter Blumencranz, MD, FACS** Medical Director BayCare Oncology Service Line Health System Medical Director The Comprehensive Breast Care Center of Tampa Bay
	Allergic Reactions and Hypersensitivity	**Tanya Laidlaw, MD, FAAAAI** Director of Translational Research, Division of Allergy and Clinical Immunology Chief, Section of Clinical and Translational Sciences Division of Allergy and Clinical Immunology Brigham and Women's Hospital Associate Professor Harvard Medical School
	Risk Mitigation Strategies	**Jorge Ferrer, PhD**
	Clinical Perspective	**Barbara Smith, MD, PhD** Director, Breast Program Massachusetts General Hospital Massachusetts General Hospital Trustees Chair in Breast Surgery Professor of Surgery Harvard Medical School
11:00 a.m.	Clarifying Questions to the Applicant	
11:45 a.m.	**BREAK**	
12:00 p.m.	**FDA PRESENTATIONS**	
	Clinical Overview	**Shane Masters, MD, PhD** Clinical Team Leader DIRM, OSM, OND, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

	Statistical Designs and Review of Efficacy Results	**Sue-Jane Wang, PhD** Deputy Division Director Division of Biometrics 1 Office of Biostatistics Office of Translational Sciences CDER, FDA
	Risk Management Considerations	**Anil Rajpal, MD, MPH** Deputy Division Director for Safety DIRM, OSM, OND, CDER, FDA
1:00 p.m.	Clarifying Questions to FDA	
1:30 p.m.	**LUNCH**	
2:30 p.m.	**OPEN PUBLIC HEARING**	
3:30 p.m.	Charge to the Committee	**A. Alex Hofling, MD, PhD**
3:45 p.m.	Questions to the Committee/Committee Discussion	
4:30 p.m.	**BREAK**	
4:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:30 p.m.	**ADJOURNMENT**	