

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

***Medical Imaging Drugs Advisory Committee (MIDAC) Meeting***

March 5, 2024

**DRAFT AGENDA**

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*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.*

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

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**DRAFT AGENDA (cont.)**

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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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**DRAFT AGENDA (cont.)**

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**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**