

## Mid-Cycle Communication Telecon

**Application type and number:** BLA 125603

**Product name:** Autologous chondrocytes seeded on a porcine-derived collagen membrane

**Proposed Indication:** Repair of symptomatic, full-thickness cartilage defects (single or multiple) of the knee, with or without bone involvement (b) (4) in adults

**Applicant:** Vericel Corporation

**Meeting date & time:** June 29, 12:00 to 1:00 PM

**Committee Chair:** John Terrig Thomas

**RPM:** Jean Gildner

### **FDA Attendees:**

John Terrig Thomas Ph.D (BLA Review Committee Chair)

Carolyn Yong PhD (CMC)

Malcom Moos MD, PhD (CMC)

Michael Yao MD (Clinical)

Bruce Schneider MD (Clinical)

Meghna Alimchandani MD (Pharmacovigilance)

Jean Gildner (RPM)

Christopher Sese (Eastern Research Group, Inc.)

Azada Hafiz (Office of Program and Strategic Analysis)

James Kenney (Lab of Microbiology, In-Vivo Testing and Standards)

William McCormick (Division of Biological Standards and Quality Control)

Hyesuk Kong (DBSQC, Product)

Simleen Kaur (Lab of Microbiology, In-Vivo Testing and Standards)

### **Agenda:**

#### **1. Significant issues identified to date:**

##### CMC:

1. Cellular Component
  - a. (b) (4) sterility testing validation
  - b. The 483 responses are under review
2. Membrane component
  - a. Genotoxicity and (b) (4) testing
  - b. (b) (4) Lot Release Testing
  - c. (b) (4) specification
  - d. (b) (4) testing acceptance criteria
  - e. FDA Form 483 observations
  - f. ACI-Maix (Matricel) manufacturing questions

Pre-Clinical: No current outstanding issues

Clinical:

1. No outstanding IRs
2. Preliminary review committee thinking regarding risk management

**2. Major safety concerns identified to date:**

No major safety concerns identified

**3. Outstanding IRs:**

Those above identified related to CMC issues

**4. New Information Requests:**

Please submit the proposed training materials for review. Please submit the proposed HCP training materials for review.

**5. Proposed date(s) for the late-cycle meeting:**

September 20, 2016