

T 910.16: FILING MEETING SUMMARY

Application type and number: BL 125657/0
Product name: Allogeneic HPC, Cord Blood
Proposed indication: For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment
Applicant: MD Anderson Cord Blood Bank
Meeting date & time: August 8, 2017 14:00-15:00 WO-71 Rm 1206
Meeting Chair: **Mercy Quagraine, Ph.D.**
Meeting Recorder: Virginia Ocampo, MT (ASCP)
Background: Original BLA submission

Table 1: Review Committee and Discipline Filing Decision Summary

Discipline/Organization	Name [with credentials (not title)]	Attended meeting	Fileable	RTF	Deficiencies Identified
Regulatory Project Manager (RPM)	Virginia Ocampo	✓			
Chair	Mercy Quagraine, PhD	✓	✓		
Division Director/Deputy	Raj Puri, MD, PhD				
Office Director	Wilson W. Bryan, MD	✓			
Clinical Reviewer	Meghna Alimchandani, MD	✓	✓		
CMC Reviewer	Prajakta Varadkar, PhD	✓	✓		✓
CMC (Flow) Reviewer	Heba Degheidy, PhD	✓	✓		
CMC (Sterility) Reviewer	Shy-Ching Lo, PhD	✓	✓		
Pharm/Tox Reviewer	Jinhua Lu, PhD	✓	✓		
DHT Reviewer	Hanh Khuu, MD	✓	✓		✓
OCBQ/DMPQ RPM	Sarah Lee	✓			
OCBQ/DMPQ Reviewer (Facilities/CMC Reviewer & Lead Inspector)	Joyce Rockwell	✓			
OCBQ/DMPQ/PRB Reviewer (Facilities/CMC Reviewer & Inspector)	Bradley Dworak	✓			

Discipline/Organization	Name [with credentials (not title)]	Attended meeting	Fileable	RTF	Deficiencies Identified
OCBQ/APLB Reviewer	Michael Brony	✓			
OCBQ/DBSQC Reviewer (Laboratory Quality and Product Testing)	Varshah Garnepudi	✓			
Statistical Reviewer of clinical data	Yuqun (Abigail) Luo	✓			
Other Attendees OTAT/IOD OTAT/DHT OTAT/DCGT OTAT/DCEPT OCBQ/DMPQ OTAT/DCGT OCBQ/DMPQ OTAT/DCEPT OTAT/DCEPT OTAT/DCEPT OTAT/DCEPT	Kimberly Benton, PhD Scott Brubaker Mohammed Heidaran, PhD Larissa Lapteva, MD Laurie Norwood Steven Oh, PhD Carolyn Renshaw Laura Ricles, PhD Mercedes Serabian, MS, DABT Iwen Wu, PhD Lei Xu, MD				

MEETING SUMMARY

The meeting began with chair discussing the objective of the meeting which is to decide if the submission is fileable. The Filing Meeting Agenda template with discussion items below was covered during the meeting. Each review member was requested to give an overview of their initial review findings and their recommendation as to the fileability of the BLA. The Chair reminded reviewers to complete the appropriate Filing checklist with concurrence to be uploaded into Sharepoint folder.

1. Does the application, on its face, appear to be suitable for filing or is the application unsuitable for filing and will require a RTF letter?

Discussion: Overall, there was concurrence from all disciplines that this BLA submission may be filed.

2. If fileable, list any substantive deficiencies or issues that have significant impact on the ability to complete the review or approve the application:
 - a. CMC/Product – shipping validation was deficient, information request will be communicated to the applicant to resolve issues (PrajaktaVaradkar)
 - b. CMC/Flow – (b) (4) software to be used in the CD34 flow enumeration will be clarified from the applicant (Heba Degheidy).

- c. CMC/Sterility – The sterility testing procedure of (b) (4) culture vial is not considered as optimal sensitivity for the sterility test of the processed Cord Blood (CB). Testing (b) (4) RBC from CB processing as the surrogate for sterility testing of the final CB product need to be conducted with at least (b) (4) RBC specimen volume. No new validation study is needed. (Shy-Ching Lo)

3. All information requests sent to RPM during the review period should copy the chair and discipline supervisor. Communications will be uploaded into separate folder in Sharepoint according to discipline for ease of tracking information requests and applicant response.

4. Action Items:

- Team recommended BLA was fileable; deficiencies present were review issues.
- RPM provided timeline for deficiency comments to accompany filing letter.
- DMPQ requested Midcycle meeting be moved to January 2018; December 7, 2017 date was too early. RPM will set new date and inform team.
- Placeholders have been set for monthly meetings; would be canceled if not needed.
- Request for Information/telecons with applicant would be arranged through RPM; BLA chair would be copied on emails; review discipline lead would attend telecons.

5. Milestone Schedule

Day 0	Application Receipt	June 26, 2017
By Day45 (30)*	Filing Meeting	August 8, 2017
By Day 60	Post draft Filing Letter in Sharepoint	Wednesday, August 9, 2017
	Reviewers' initial letter ready comments due:	Tuesday, August 15, 2017
	Supervisory review of letter due:	Friday, August 18, 2017
	Send to signatory due:	Monday, August 21, 2017
	Send Filing Letter to applicant	Friday, August 25, 2017
By End of Month 5(3)*	Mid-Cycle Meeting Internal	December 7, 2017** to be re-scheduled early January 2018

Scheduled Team Meetings:

Friday, September 29, 2017 @ 10:00-11:00 Rm 1206
 Wednesday, October 25, 2017 @ 13:00-14:00 Rm 1206
 Tuesday, November 14, 2017 @ 14:00-15:00 Rm 1206

Discussion:

**It was suggested that Mid-cycle meeting be scheduled on the first or second of January 2018, inspection will then be scheduled accordingly (Joyce Rockwell).