

Teleconference with MD Anderson Cord Blood Bank

Application number: BLA 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: October 11, 2017 at 13:00-14:00
Committee Chair: **Mercy Quagraine, Ph.D.**

FDA Participants:

Shy-Ching Lo, MD, CMC (Sterility) Reviewer, CBER/OTAT/DCGT
Heba Degheidy, PhD, CMC (Flow) Reviewer, CBER/OTAT/DCGT
Virginia Ocampo, MT, CBER/OTAT/DRPM
Mercy Quagraine, PhD, BLA Chair/Product Reviewer, CBER/OTAT/DCGT
Joyce Rockwell, Facilities/CMC Reviewer & Lead Inspector, CBER/OCBQ/DMPQ

MD Anderson Cord Blood Bank Participants:

Dr. Elizabeth Shpall (CBB Director)
Dr. Chitra Hosing (CBB Medical Director)
Suzanne Dworsky (CBB Administrator)
Jeffrey Wilson (Assistant Director)
Donna Reieux (Manager, CBB Quality Assurance)
Erin Eaton (CBB Program Manager)
Mil Fontenot (Supervisor, Laboratory)
Theresa Tompkins (Supervisor, Quality Control)
Krystle Pool (Manager, CBB Collections)
Silviea Rosu (Quality Assurance)
Ankita Desai (Quality Assurance)

Items discussed:

I. Chemistry Manufacturing and Controls (Flow):

The following information requests and clarification were discussed during the teleconference (Heba Degheidy, CMC reviewer):

1. *Please provide information on the number of flow cytometry instruments (b) (4) that are currently in place and used for CD34 enumerations*

- The applicant responded that (b) (4) instrument is being used.
2. *Please provide a detailed narrative description on how the validation study was conducted for CD34 (b) (4) and viability (operators, lots of reagents, runs, days etc.). Please include a summary of the testing performed in the single platform validation for CD34 analysis (tabular format would be ideal).*
 - The applicant will provide the information as an amendment to the BLA.
 3. *We recommend that you use the single platform with (b) (4) clinical software for their validation study as this is the software that the CD34 510(k) was cleared on.*
 - Applicant agreed to use single platform with (b) (4) clinical software for the validation.
 4. *Recommendations regarding the provided linearity study for viable CD34, (b) (4) and viability:*
 - A minimum of (b) (4) data points should be tested in the proposed linearity assays.
 - Linearity data for the viable CD34+ (b) (4) data should be presented as the found percent viability against the expected percent viability
 - Applicant agreed to re-analyze the validation data and will communicate this before submitting the amendment.
 5. *Please submit all missing SOPs and accompanying worksheets for review e.g. CBB012.013 (b) (4) Cytometer: Preparation of Reagent and Samples and Reagent Qualification"*
 - Applicant will provide missing SOPs on the next amendment.
 6. *Please submit your SOP for qualification of new reagent lot and establish acceptance criteria for acceptable difference between the old and new reagent lots.*
 - Applicant will provide SOP for qualification of new reagent lot.
 7. *Please note that the holding time (b) (4) sample acquisition should not exceed (b) (4) as stated in the CD34 package insert.*
 - Applicant will clarify sampling time, staining, acquisition and analysis of samples in a table format.

8. *Please confirm if you use (b) (4) of sample when running the assay and update the SOP to reflect that (b) (4) of sample is used for staining as stated in the CD34 enumeration kit's package insert.*
 - Applicant will clarify sample volume used for staining.
9. *Please clarify the number of clinical samples as well as controls (low, mid and high) that were used for instrument performance testing.*
 - Applicant will clarify number of samples and controls used for CD34
10. *Please note that the FDA approved (b) (4) from (b) (4) should be used to obtain all flow cytometry values including (b) (4)/Total viability acquired on the (b) (4) clinical software (single platform).*

II. Facilities inspection:

Joyce Rockwell inquired if the applicant is “inspection ready” as indicated on the FORM FDA 356h or had the facility been affected by the recent hurricane. The applicant replied that their facility was unscathed and was very fortunate. Joyce mentioned that the target pre-license inspection date is January 22 – 26, 2018 and she will be communicating with the applicant in November regarding the timeline for the facilities inspection and items that the applicant will need to pre-stage/have prepared for the inspection.

The meeting ended cordially, FDA mentioned that there may be more interactive communication during the review process of the BLA. The applicant mentioned that the amendment to the information requested in the filing letter has been submitted.