

# **Sponsor Telecon, August 31, 2011 - Hemacord**

**BLA #: 125397**

**Teleconference Date: August 31, 2011**

## **Participants:**

Pablo Rubinstein, M.D. – Vice President, New York Blood Center (NYBC) and Director, National Cord Blood Program (NCBP)

Eva Quinley – Senior Vice President (NYBC), Quality & Regulatory Affairs

Andromachi Scaradavou, M.D. – Medical Director (NCBP)

Michael Zdanowski – Director of Operations (NCBP)

Michael Tarnawski – Director, IT (NCBP)

Ludy Dobrila, Ph.D. – Associate Director, Processing (NCBP)

Kristin Keshishian – Quality Specialist, Cord Blood (NYBC)

Edwin W. Streun – Director, Regulatory Affairs-I (NYBC)

Christine Driscoll – Director, Regulatory Affairs-II (NYBC)

## **NMDP Participants**

John P. Miller, M.D., Ph.D. – VP & Senior Medical Director

Kathy Welte – Director, Business Development

Lisa Phillips Johnson – Director, Regulatory Compliance

Amy Foley

## **CIBMTR Participants**

J. Douglas Rizzo, M.D, M.S. – Associate Scientific Director

Willis Navarro, M.D. – Medical Director, Transplant Services

## **FDA Participants**

Karandish, Safa; Ghosh, Joydeep; Quagraine, Mercy; Benton, Kimberly

## **Summary of Discussion:**

### **1. Latest Bacteriology Retest Results ---(b)(4)---**

Discussion Summary: The sponsor now has the data on ---(b)(4)-- and it could be detected within (b)(4) under their assay conditions. We told them to submit the data for our review.

### **2. Studies on additional organisms**

#### **Discussion Summary:**

i) The sponsor wanted to know if they could use any other species in place of -----(b)(4)----- as it is not a clinically relevant microorganism. We told them that they could use any other microorganism with a ----(b)(4)---- similar to --- ----(b)(4)----- . However, we would prefer to see data using a slow growing mold as the incubation temperature on the ----(b)(4)---- is not optimum for many mold species. We also told them that the sponsor could discuss this issue directly with --- -(b)(4)---- as they would have more knowledge on the ----(b)(4)---- of microorganisms grown in the -----(b)(4)-----.

ii) The sponsor wanted to know if they fail to detect -----(b)(4)----- -- ----- within (b)(4) using ----(b)(4)---- then how would it impact the BLA approval. We told them that we need to have the data on -----(b)(4)---- ----- to make our decision.

### **3. We appreciate further clarification regarding the following two items:**

According to SOP CB37.0023.4, step 6.1.5.4, cord or maternal samples that are positive for antibody to Chagas disease can be released to the search inventory as ineligible donor. However, SOP CB41.0002.2, step 6.4.1.1.1 states that CB units released for transplantation must be non-reactive for anti-Trypanosoma Cruzi. Please provide clarification regarding this discrepancy and submit the revised document.

*The sponsor will correct the information in SOP CB41.0002.2 and will submit the revised procedure.*

We note that you consider units to be qualified for licensure if all the required donor testing has been performed in accordance with the test kit manufacturer's instructions and the donor is determined to be eligible. We also note that for some units that are in the existing inventory, retrospective testing for HIV/HCV NAT may be performed using frozen maternal samples (SOP CB37.0023.4, step 6.1.5.9.1). We recommend that you include additional details regarding the donor eligibility determination when retrospective testing for HIV/HCV NAT has been performed

using frozen samples that may have been in storage beyond the manufacturer's recommended storage time.

*The sponsor is developing a plan and will submit the revised SOP when completed.*

Page Last Updated: 09/24/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [ةيبرعلا](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [ىسراف](#) | [English](#)