



MEMORANDUM

From: Wilson W. Bryan, M.D., Director
Division of Clinical Evaluation and Pharmacology / Toxicology, OCTGT, CBER
Date: August 17, 2016

BLA/ STN#: 125594 / 0
Applicant Name: Cleveland Cord Blood Center
Action Goal Date: September 8, 2016
Proprietary Name/ Established Name: Clevecord
Non-Proprietary name: HPC, Cord Blood

Indication: HPC, Cord Blood is an allogeneic cord blood hematopoietic progenitor cell therapy intended 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. The risk benefit assessment for an individual patient depends on the patient characteristics, including disease, stage, risk factors, and specific manifestations of the disease, on characteristics of the graft, and on other available treatments or types of hematopoietic progenitor cells.

Pharmacology / Toxicology Reviewer: Shamsul Hoque, Ph.D.

Pharmacology / Toxicology Team Leader: Becky Robinson, Ph.D.

Clinical Reviewer: Steve Winitsky, M.D.

Statistical Reviewer: Stan Lin, Ph.D.

Statistical Team Leader: Shiojjen Lee, Ph.D. (statistical)

Material Reviewed / Consulted: Pharmacology / Toxicology Review (July 13, 2016)
and Clinical / Statistical Review (August 15, 2016)

I agree with the conclusions of the pharmacology / toxicology review and the clinical / statistical review. I agree with the recommendation for approval as stated in the clinical / statistical review memo dated August 15, 2016, and have no additional comments.

Wilson W. Bryan, M.D.