



MEMORANDUM

From: Wilson W. Bryan, M.D., Director,
Division of Clinical Evaluation and Pharmacology / Toxicology, OCTGT, CBER
Date: January 28, 2016

BLA/ STN#: 125585 / 0

Applicant Name: Puget Sound Blood Center

Action Goal Date: January 28, 2016

Proprietary Name/ Established Name: None

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: Jinhua Lu, Ph.D.

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

Clinical and Statistical Reviewers: Agnes Lim, M.D. (clinical); Yuqun Abigail Luo, Ph.D. (statistical)

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

Material Reviewed / Consulted: Pharmacology / Toxicology Review (November 19, 2015) and Clinical / Statistical Review (January 26, 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 January 26, 2016, and have no additional comments.

Wilson W. Bryan, M.D.