



FDA Approves New York Blood Center's HEMACORD™ for Stem Cell Transplantation

First FDA-Licensed Stem Cell Product

NEW YORK, Nov. 10, 2011 /PRNewswire-USNewswire/ -- The Food and Drug Administration has licensed HEMACORD™ (Hematopoietic Progenitor Cells-Cord, HPC-C) for allogeneic hematopoietic (blood-forming) stem cell transplantation, the first such approval of a stem cell product in the world.

According to the Food and Drug Administration's notification to New York Blood Center (NYBC), HEMACORD™ is "indicated for use in unrelated donor hematopoietic progenitor cell transplantation procedures... in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment." Such conditions could include patients with hematologic malignancies, primary immunodeficiency diseases, bone marrow failure, and beta-thalassemia. HEMACORD™ is indicated for use with children.

"We are thrilled to be the first public cord blood bank with an FDA-licensed product for transplantation," said Christopher D. Hillyer, MD, President and CEO of New York Blood Center (NYBC). Since 1996, NYBC's National Cord Blood Program (NCBP) at the Howard P. Milstein National Cord Blood Center has provided cord blood units for transplantation under an Investigational New Drug (IND) exemption from the FDA. The mission of the NCBP is to facilitate access to cord blood as a treatment option for patients, notably those from diverse ethnic backgrounds.

To obtain FDA licensure of HEMACORD™, all collection and manufacturing conditions of the cord blood units met FDA standards for product potency, purity and efficacy, and patient safety. NCBP's Biologics License Application (BLA) included extensive documentation of the systems and controls used, and the validations performed to ensure compliance with FDA standards in all steps of manufacturing (collections, processing, testing, typing, cryopreservation, storage, distribution and shipping) cord blood units for clinical use. Further, it included the safety data from the transplantation of more than 4,000 cord blood grafts. In advance of the BLA submission, NCBP moved its entire manufacturing and storage resources to a state-of-the-art facility in Long Island City, New York.

"The application process has been a rigorous and educational one for all of us at the National Cord Blood Program," said Pablo Rubinstein, MD, NYBC Vice President and Program Director of NCBP. "We have always understood that providing high quality cord blood units for clinical use requires thorough scientific and technical definitions of methods, detailed analysis of results, and hard work. Achieving

systematic compliance with FDA Good Manufacturing Practices and Good Tissue Practices offers further assurance of the consistency, potency, purity, safety and efficacy of NCBP cord blood units."

About National Cord Blood Program (NCBP): Launched in 1992, New York Blood Center's (NYBC) National Cord Blood Program (www.ncbp.us) at the Howard P. Milstein National Cord Blood Center, was the first established umbilical cord blood bank to collect, process, test and store cord blood units and make them available for transplantation to patients in need of hematopoietic stem cell transplantation. The NCBP has provided more than 4,200 cord blood units for transplantation worldwide since its inception. NCBP is a public cord blood bank and accepts requests from Transplant Centers and Registries all over the world. Cord blood units can be accessed and searched directly through NCBP's WebSearch (<https://tc.placentalblood.org/>). Cord blood units can also be accessed through Bone Marrow Donors Worldwide (BMDW), the National Marrow Donor Program, or by calling 718-752-4710 or 866-767-6227.

About New York Blood Center: New York Blood Center (NYBC), one of the nation's largest non-profit, community-based blood centers, has been providing blood, transfusion products and services to hospitals since 1964. NYBC currently serves more than 20 million people in New York City, Long Island, the Hudson Valley, New Jersey, and parts of Connecticut and Pennsylvania. NYBC is also home to the Lindsley F. Kimball Research Institute and the National Cord Blood Program at the Howard P. Milstein National Cord Blood Center, the world's largest public cord blood bank. NYBC provides medical services and programs (Clinical, Transfusion, and Hemophilia Services) through our medical professionals along with consultative services in transfusion medicine. Please visit us on Facebook at www.Facebook.com/newyorkbloodcenter. Follow us on **Twitter: @NY_BloodCenter**.

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