U.S. Food and Drug Administration
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FDA NEWS RELEASE
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FDA approves first cord blood product

The U.S. Food and Drug Administration today approved HEMACORD, the first licensed hematopoietic progenitor cells-cord (HPC-C) cell therapy.

HEMACORD is indicated for use in hematopoietic stem cell transplantation procedures in patients with disorders affecting the hematopoietic (blood forming) system. For example, cord blood transplants have been used to treat patients with certain blood cancers and some inherited metabolic and immune system disorders.

"The use of cord blood hematopoietic progenitor cell therapy offers potentially life-saving treatment options for patients with these types of disorders," said Karen Midthun, M.D., director, FDA's Center for Biologics Evaluation and Research.

HEMACORD contains hematopoietic progenitor cells (HPCs) from human cord blood. Cord blood is one of three sources of HPCs used in transplants; the other two are bone marrow and peripheral blood. Once these HPCs are infused into patients, the cells migrate to the bone marrow where they divide and mature. When the mature cells move into the bloodstream they can partially or fully restore the number and function of many blood cells, including immune function.

In an effort to assist manufacturers in applying for licensure for certain cord blood units, FDA issued the 2009 guidance document entitled "Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications." FDA instituted a two-year phase-in period for HPC-C manufacturers to submit either a license application or an investigational new drug application. That phase-in period ended Oct. 20, 2011, and these manufacturers now must submit such applications.

Approval of HEMACORD was based on reliance on safety and effectiveness data submitted to a public docket and data submitted in the license application demonstrating compliance with other regulatory requirements. This is the first approval of a license application for cord blood.

HEMACORD has a boxed warning regarding the risks of Graft Versus Host Disease (GVHD), engraftment syndrome, graft failure, and infusion reactions, each of which may be fatal. Patients who receive HEMACORD should be monitored carefully. A risk benefit assessment, unit selection and administration of HEMACORD should be done under the direction of a physician experienced in hematopoietic stem cell transplantation.

HEMACORD is manufactured by the New York Blood Center, Inc., based in New York, NY.