FDA approves DUCORD product for stem cell transplants

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Duke University School of Medicine has received approval from the Food and Drug Administration to market DUCORD, a stem cell product derived from umbilical cord blood, for use in transplants between unrelated donors and recipients.

DUCORD is approved for use in hematopoietic stem cell transplantation for patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

The approval marks a significant achievement for Duke and the Carolinas Cord Blood Bank (CCBB), a not-for-profit, public cord blood bank at the medical school, which has pioneered cord blood transplants for children and adults with cancer, blood disorders and inherited diseases. Only two other cord blood banks in the United States have received FDA approval to market similar stem cell products.

"This approval and the quality it reinforces are lynchpins in Duke Medicine's commitment to developing and translating innovative cellular therapies," said Victor J. Dzau, M.D., chancellor for health affairs at Duke University and president and CEO of Duke University Health System.

"This is a major milestone in the history of the university and a significant step forward in the field of regenerative medicine at Duke and elsewhere," said Nancy Andrews, M.D., dean of the Duke University School of Medicine

Hematopoietic stem cells, derived from cord blood and produced in the bone marrow, are able to renew themselves and differentiate into specialized cells. When transplanted in people with lymphoma, leukemia, immune disorders and genetic conditions, these robust cells can establish a life-saving new blood and immune system.

Blood from babies' umbilical cords, which was once discarded, is rich in hematopoietic stem cells. Joanne Kurtzberg, M.D., director of Duke's Pediatric Blood and Marrow Transplant Program, was a trailblazer in their use for transplants and was a founder of the public bank through CCBB. Kurtzberg has remained at the forefront of expanding the use of cord blood for patients with life-threatening diseases.

"The licensure of DUCORD is a reflection of the dedication and hard work of the entire CCBB staff over the past decade," said Kurtzberg, medical director and founder of the CCBB. "Licensure enables the CCBB to continue to provide cord blood units to patients in need of a donor for unrelated transplantation. We feel that going through the licensure process has strengthened and improved our operations. In addition, it will allow the CCBB to provide the highest quality cord blood units as source material for new clinical applications in cellular therapies in the future."

To receive the FDA license, the CCBB submitted an application documenting the steps, policies and procedures required for manufacturing high quality cord blood units, including collection, processing, testing, storing and distributing the cells.

"FDA approval is a major statement about the quality of the product and the methods used to produce it," said Robert Califf, M.D., Duke's vice chancellor for clinical research.

Prior to receiving the FDA license, CCBB provided more than 1,500

high quality cord blood units throughout the world under an FDA Investigative New Drug application. Currently, all CCBB units are listed on the National Bone Marrow and Donor Program's "Be the Match" registry, a central database for transplant centers to search and request cord blood units for patients in need of unrelated donors for transplantation.

The CCBB is also a member of the National Cord Blood Inventory of the C.W. Bill Young Cell Transplantation Program, administered through the U.S. Department of Health and Human Services.

Kurtzberg said the CCBB staff is committed to advancing the benefits of stem cells isolated from umbilical cord blood, and to improve the lives of those inflicted with inherited and acquired serious and life-threatening medical conditions.

"Dr. Kurtzberg's program has successfully balanced the urgent pressure to innovate and find new cures for our patients with the painstaking care that prioritizes patient safety and permits rigorous regulatory review," Dzau said.

Provided by Duke University Medical Center