



Cleveland Cord Blood
CENTER

Save a Cord. Save a Life.

CCBC Connection



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FDA approves CLEVECORD™ for stem cell transplants

In September, the U.S. Food and Drug Administration (FDA) issued a biologics license to the Cleveland Cord Blood Center (CCBC) for CLEVECORD™, a stem cell product (HPC, Cord Blood) derived from umbilical cord blood. Under this license, CCBC is authorized to manufacture CLEVECORD for use in unrelated hematopoietic cell transplantation in patients with disorders affecting the hematopoietic system such as leukemia, lymphoma and immune system disorders.

"Obtaining FDA licensure for CLEVECORD is reflective of the Cleveland Cord Blood Center's dedication to meeting the highest quality standards in the industry for distribution of our cord blood products to transplant centers throughout the U.S. and around the world," said Wouter Van't Hof, the CCBC's Cord Blood Bank Director. "The ability to meet such standards is indicative of the commitment of our organization to providing high quality transplant options to patient populations that are underserved in hematopoietic transplantation. It also stages the pursuit of new life-saving and life-enhancing research and product development opportunities."

The organization's cord blood collections represent a diverse cross-section of donor ethnicity to support transplant needs, including patients in the underserved African-American community.

"Since CCBC's founding by Mary Laughlin, M.D., who performed one of the world's first successful umbilical cord blood



FDA approval of CCBC's CLEVECORD reflects high quality standards

stem cell transplants on an adult leukemia patient in 1993, a commitment to organization-wide quality has been pervasive," said Executive Director Marcie Finney. "The FDA approval of CLEVECORD is a testament to the dedication and mission of our team to the possibility of saving lives."

A standard of quality to help save lives

Since its establishment in 2008, the mission of the Cleveland Cord Blood Center (CCBC) has been to provide quality cord blood units for transplant patients served – from collection to distribution.

"Having recently obtained FDA licensure for our cord blood products, we have come to appreciate the rigor and documentation necessary to objectively show the FDA, and ourselves, that CCBC's processes consistently meet the quality standards for safety and efficacy of our biological drug product," said Lisa Phillips Johnson, Quality and Regulatory Affairs Director.

Johnson, who joined the organization in 2015, is responsible

for the management of quality and regulatory compliance. She, along with three other members of the quality systems department team, help ensure that CCBC processes consistently meet quality standards.

"It is fair to say that FDA quality standards are recognized world-wide," she added. "As the cellular industry has developed, CCBC has been part of the larger community of U.S. and international cord blood banks, working collaboratively with our U.S. and international partners to support donors and recipients, with distribution of CCBC units to patients within the U.S. and 14 countries worldwide."

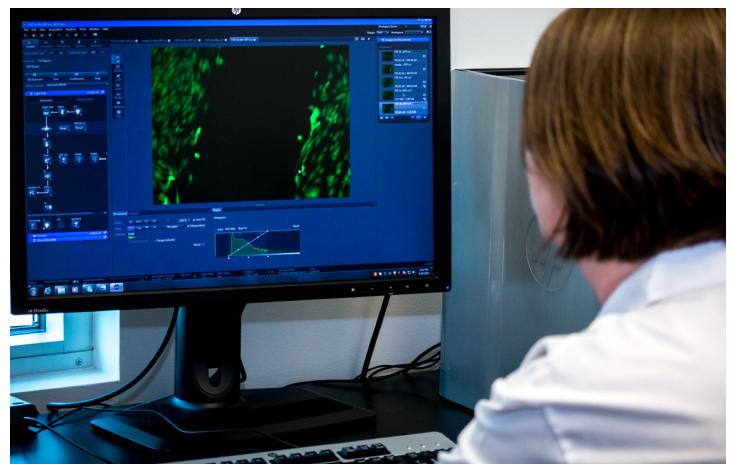
Research focuses on cord blood cellular treatments

At the Global Cardiovascular Innovation Center in Cleveland's University Circle area, Cleveland Cord Blood Center (CCBC) Research and Development laboratory scientists are currently exploring regenerative cell therapies for diseases ranging from Parkinson's Disease and HIV/AIDS to diabetes and wound healing.

Jeong Su Do, Ph.D., is spearheading the generation of special immune cells called 'inducible T regulatory (iTreg) cells for patients with immune disorders like Type 1 diabetes. The hope is that iTregs from cord blood will dampen the effects of diabetes in the pancreas, so the patient is not dependent on daily insulin injections.

Pre-clinical studies led by Twishasri Dasgupta, Ph.D., are investigating stem cell therapy for patients with Parkinson's Disease. Here Dr. Dasgupta is studying a 'dual-cell' treatment to support and regenerate special cells in the brain that produce dopamine.

Dr. Dasgupta is also working to identify cord blood grafts that are naturally resistant to HIV infection for transplantation in patients with blood disorders who are infected with this virus. These clinical trials will be conducted at seven U.S. centers and may transform the treatment of HIV infected patients.



CCBC scientists are exploring regenerative stem cell therapies to address unmet medical needs

Jennifer Greene-Roos, Ph.D., is conducting studies to develop novel, off-the-shelf wound healing products that are very effective in killing bacteria, and treating patients with infected non-healing wounds.

"Plans are to take the researchers' initial proof of concept to intellectual property development, and ultimately take these discoveries into clinical trials that aim to prove safety and efficacy in the clinical setting," explained Dr. Greene-Roos. "These 'bench to bedside' studies are very focused on expanding the use of cord blood as treatment in novel medical applications."



Susan Fister

A survivor's appreciation for the cord blood gift of life

Susan Fister received a cord blood stem cell transplant over a decade ago when two bone marrow transplants failed to treat her cancer. Cleveland Cord Blood Center Founder Mary Laughlin, M.D., performed Fister's cord blood transplant in 2004.

"I credit the cord blood transplant with making it possible for me to see both my sons graduate from college and get married," she said. Now with three young granddaughters and one of her sons in medical school, she is an enthusiastic advocate of cord blood donation. "I have the bonus of having blood that is young. It's a part of me now."

Fister noted that she wouldn't be here today if it wasn't for public cord blood banks like the Cleveland Cord Blood Center. When she talks with expectant parents, she encourages them to donate their babies' umbilical cord blood. Otherwise, she points out, the cord blood would be discarded.

"Every day is a gift," she concluded. "I am grateful for public cord blood banks and the parents who donate their babies' umbilical cord blood so that the lives of others may be saved. The Cleveland Cord Blood Center's tagline 'Save a Cord. Save a Life,' echoes my experience with this life-saving gift."