

Cryo-Cell Announces Partnership With National Institutes of Health

Collaboration will evaluate menstrual stem cells for future potential breast cancer therapy

Cryo-Cell® International Inc. and the National Institutes of Health (NIH) Clinical Center announced on November 18, 2008 a research partnership to conduct an exploratory study to determine the homing capabilities of Cryo-Cell's proprietary Endometrial Menstrual Stem Cells (MenSCs) in a breast cancer model.

The NIH Clinical Center research team, led by Dr. Joseph Frank, will label the MenSCs with iron oxide nanoparticles, which will make it possible to track the distribution of the MenSCs in the body using magnetic resonance imaging (MRI). The ability to use MRI to monitor the migration of the MenSCs may provide the basis for determining the future utility of MenSCs in the treatment of disease.

"We know that the MenSCs are capable of differentiating into different cell types, and that they have the ability to divide rapidly," said Julie Allickson, Ph.D., Vice President of Laboratory Operations and Research and Development at Cryo-Cell. "The study may provide the basis for determining future use of these cells to treat diseases."

Clinical non-invasive imaging techniques that allow for long term tracking of stem cells *in vivo* do not currently exist. The Experimental Neuroimaging Section of Radiology and

Imaging Sciences at the NIH Clinical Center has developed techniques to label stem cells with the FDA approved agent, ferumoxides (FE), which is commonly used as a contrast agent with magnetic resonance (MR) imaging. By using FE, researchers in the Experimental Neuroimaging Section of the LDRR are able to track the temporal and spatial migration by MRI.

Dr. Frank and his colleagues in the Experimental Neuroimaging Section of Radiology and Imaging Sciences will evaluate the labeling efficiency of MenSCs to determine if there is any alteration in differentiation potential, proliferative capacity, metabolic alterations, apoptosis rate and/or an increase in iron content of the tracked cells compared to unlabeled cells.

Following the *in vitro* evaluation of FEPro (ferumoxides complexed to protamine sulfate) labeled endometrial cell function, if the MenSCs are not altered by FEPro labeling, a series of *in vivo* MRI studies will be conducted in rodent tumor models to determine if the magnetically labeled cells will migrate to and integrate into the tumor. Further studies may be added that will explore the therapeutic uses of MenSCs at the molecular level, as gene therapy or delivery vehicles for nanotherapeutic chemotherapeutic agents to treat cancer if the present research supports such studies.

Cryo-Cell International and EndGenitor Technologies Announce Research Collaboration

Research Study Will Explore Therapeutic Cellular Platform Utilizing Cord Blood and Menstrual Blood Derived Stem Cells in the Formation of Emergent Vascular Structures

Cryo-Cell International, Inc. and EndGenitor Technologies, Inc. announced on August 21, 2008, a new research collaboration to co-develop a combined cellular platform therapeutic for rapidly forming vasculature in injured tissues. Currently, intense research into the mechanisms of initiation of angiogenesis and the repair of damaged vasculature is underway in order to identify the participating molecular and cellular components involved. Greater understanding of this highly-complex process is paving the way to identify novel potential therapeutics for treating cancer and cardiovascular disease.

The research will focus on the utilization of cord blood and menstrual blood derived cells, known as ECFCs® and MenSCs, respectively. ECFCs are cord blood-derived endothelial colony-forming cells. ECFCs are currently in pre-clinical development by EndGenitor for cardiovascular and other therapeutic applications. MenSCs, which were discovered and developed by Cryo-Cell, are primitive mesenchymal progenitor cells found in menstrual blood and are easily retrievable without invasive techniques.

"We think the project has significant potential, as both ECFCs and MenSCs contribute to angiogenesis *in vivo*, which underscores the importance of further study into the potential synergy of these cells in the formation of vasculature," said Dr. Julie Allickson, Vice President of Laboratory Operations and Research and Development at Cryo-Cell, which developed and maintains proprietary intellectual property (IP) on MenSCs.

"EndGenitor is extremely pleased to have the opportunity to partner with Cryo-Cell International in the development of its regenerative medicine product lines. The synergy resulting from Cryo-Cell and EndGenitor's joint research efforts, and complimentary expertise, is expected to significantly impact pre-clinical development timelines," said Dr. Paul Hyslop, Vice President of Research and Development at EndGenitor, which has developed and maintains IP on ECFCs®.

TO STAY UP-TO-DATE ON THE LATEST RESEARCH NEWS, VISIT

www.stemcellresearchnews.net

WINTER 2008

Cryo-Cell News

Partnership With National Institute of Health.....	1
EndGenitor Technologies Research Collaboration.....	1
A Message from our CEO	2
New Disease Treatments.....	2
C'ELLE Global Expansion	3
Cord Blood for Diabetes	3
Heart Valves From Stem Cells.....	4



Cryo-Cell Provides Value in Times of Economic Uncertainty

By: Mercedes Walton
Chairman and Chief Executive Officer
Cryo-Cell International, Inc.

At a time when we're all feeling the crunch of the economic down-turn, the American public is looking for increasing value from the products and services they purchase. We are all looking to make our dollar go farther and get more for our money; and rightly so.

I am sure your patients are prioritizing their spending, especially since they are about to bring a new baby into the world. It's an exciting and challenging time for them and they are probably looking to you for guidance in many areas, including whether or not – and with whom – to store their newborn's cord blood.

As an expert, you're well aware of the life-saving potential that cord blood offers to parents. For those families who understand the importance and impact of this protection, I'd like to point out some of the added value that Cryo-Cell® offers, which no other cord blood company provides.

Quality and Longevity

Quality and dependability are, of course, the main concern—and Cryo-Cell holds more quality accreditations, and has been in business longer than any other cord blood bank in the industry.

Upromise College Fund

Cryo-Cell is the exclusive Upromise® college savings plan cord blood partner and we contribute 2% of every purchase to our client's established *free* Upromise account. That's a total deposit of up to \$113, in addition to our annual storage fee contribution. At a time when paying for college is becoming less feasible for many families, this is a great way to ease this burden. This opportunity is available to anyone who wants to save for a child's college education—including parents, grandparents, extended family and friends. *Cryo-Cell has already contributed over \$250,000 towards our client's college savings plan.*

Product Guarantee and Transplant Subsidy

Cryo-Cell provides a \$50,000 Product Quality Guarantee; and we are the only company in the industry to that offers a \$10,000 Cryo-Cell Cares™ payment to our client families to offset their personal expenses for an established stem cell transplant procedure.

Client for Life Pricing

Another exclusive Cryo-Cell feature is our Client for Life™ program that locks in today's pricing for future children.

Please consider recommending Cryo-Cell International when discussing cord blood banking to your clients. Not only will you have the confidence in knowing you referred your patients to the highest quality bank, your patients will receive the best service at the highest value in these times of economic challenge and uncertainty.

Kindest Regards,


Mercedes Walton



Cord Blood Stem Cells Examined For Potential New Disease Treatments

Cryo-Cell International Supplies Cord Blood for Trials on Cerebral Palsy, Sickle Cell Disease

Researchers continue to find new avenues for the use of umbilical cord blood in a host of serious diseases, as new clinical trials are finding success in treating cerebral palsy and sickle cell anemia. Cord blood stored with Cryo-Cell has been used to support a number of clinical trials this year.

Among the growing list of successful transplants, Cryo-Cell has released their client's stem cells to a number of recent successful transplant procedures, including two cerebral palsy cases in a Duke University clinical trial, a sickle cell anemia case at North Shore Long Island Jewish Children's Hospital and an acute myeloblastic leukemia case at the Hospital Juan I. Menchaca in Mexico.

Current research is being conducted on the use of stem cells to expand the treatment possibilities, including potential treatment of cardiac and neurological diseases, among others. Cryo-Cell's U-Cord® service allows parents to collect and store their child's umbilical cord blood for the potential future medical benefit of the family.

"Cryo-Cell is pleased to be able to support these exciting clinical trials with cord blood stored at our facilities. We believe in the value of these cells and are working to further educate the public about the value of storing cord blood; it can really make the difference for a family," said Mercedes Walton, CEO, Cryo-Cell International.

Cryo-Cell continues to build a robust research portfolio with partnerships and research agreements worldwide. While continuing to study cord blood cells, the company is also looking at stem cells derived from menstrual blood (MenSCs.) Early studies of these cells have confirmed that they have the capability to differentiate rapidly and plentifully into important cells, such as bone, cartilage, fat, nerve and cardiogenic cells. These are non-controversial adult stem cells that are easy to extract and cause no pain to the donor, making them an important and potentially valuable alternative to other stem cell sources. With additional studies, the use of these cells may lead to treatments for a number of serious diseases, such as stroke, Alzheimer's and Parkinson's disease. The cells may even one day be used for customized anti-aging or sports medicine treatments.

"As part of our commitment to furthering the research, we continue to study these cells and identify opportunities for their use in new areas; combined with our research into menstrual stem cells, we are making real progress in identifying uses for adult stem cells in modern medicine," said Julie Allickson, Ph.D., Vice President of Laboratory Operations and Research and Development at Cryo-Cell.

C'ELLE

YOUR MONTHLY MIRACLE



CRYO-CELL ANNOUNCES GLOBAL EXPANSION OF C'ELLE™

Proprietary New Service to Launch in Countries in Europe, Latin America and Southeast Asia

Cryo-Cell® has formalized agreements with C'elle distribution partners in the United Kingdom, Ireland, Italy, Greece, Venezuela and Panama. Cryo-Cell's technology license partner, LifeCell Private Ltd., previously announced plans to introduce the C'elle service in India. C'elle has the potential to benefit millions of women worldwide, since stem cells found in menstrual blood may potentially be utilized in a broad range of future regenerative therapies to possibly treat a number of debilitating conditions such as heart disease, stroke and diabetes. C'elle stem cells may also have potential to be used in cosmeceutical applications such as anti-aging and wound-healing.

"We are very excited to partner with Cryo-Cell International to distribute C'elle throughout Ireland and the UK," said Michael Doherty, Managing Director, Medicare Health & Living Ltd. "Cryo-Cell International is renowned for its high standards and excellence. We believe that C'elle has the potential to revolutionize women's

health globally. This is truly a great opportunity to bring an exclusive and innovative product to the women of Ireland and the UK enabling them to store their very own portfolio of stem cells."

Cryo-Cell continues to explore new global commercial and scientific partnerships and recognizes that the regenerative potential of C'elle may one day help to advance women's healthcare around the world. With the international launch of C'elle, Cryo-Cell's global partners will have a unique opportunity to expand their business models with a proprietary and highly differentiated service.

"We believe that the globalization of C'elle may generate significant worldwide awareness and interest in the potential of future stem cell therapeutic breakthroughs," said Mercedes Walton, Chairman and CEO of Cryo-Cell International. "We are pleased that our exclusive service, C'elle, will be introduced to women in different countries around the world. This exclusive and innovative service, based on Cryo-Cell's expansive intellectual property

portfolio, provides women with the opportunity to store their own stem cells for future potential therapeutic benefit."

Studies published in the April 2008 issue of *Cell Transplantation* demonstrated that MenSCs proliferate rapidly and have significant potential to develop into multiple cell types. C'elle menstrual stem cells offer an easily accessible, non-controversial and renewable stem cell source, and these findings could mean that these cells have the future potential to treat a host of diseases.

"Clinical trials are now underway to test the safety and efficacy of stem cells found in menstrual blood (MenSCs) in animal models for diabetes, neurodegenerative and cardiovascular regenerative therapies," Walton continued. "C'elle stem cells may one day be utilized in regenerative medicine therapies to potentially treat a broad range of diseases such as stroke, Alzheimer's and Parkinson's, that afflict millions worldwide."

FOR MORE INFO ON THESE STORIES AND MORE GO TO www.stemcellresearchnews.net
TO ORDER U-CORD AND C'ELLE LITERATURE FOR YOUR PATIENTS CALL 1.888.612.3553 (option 5)

CORD BLOOD FOR DIABETES

GAINESVILLE, FL. (Ivanhoe Newswire) – Nearly three million children and adults in this country live with type 1 diabetes; a disease that will shorten their lifespan and put them at risk for kidney failure, blindness and heart disease. A medical first may come from umbilical cord blood.

Nothing stops 11-year-old Barrett Ross from playing his favorite sport, football... not even having type 1 diabetes.

"I'm just like a regular kid," he told Ivanhoe "I just get a couple more shots and a couple more pricks than other kids."

Barrett gives himself insulin shots and pricks his finger up to eight times a day. He also carefully monitors everything he eats. When Barrett was first diagnosed, his parents enrolled him in a clinical trial testing umbilical cord blood infusions.

"I contacted them immediately through e-mail and told them that Barrett was diagnosed within the last 24 hours and that we had saved cord blood," Christine Ross, Barrett's mom, recalled.

When parents choose to bank their newborn's umbilical cord blood, it can later be used for research. At the University of Florida, 20 children were given a one-time infusion of their own cord blood.

Researchers say stem cells in the blood may slow the immune attack of diabetes so the pancreas destroys fewer "good" cells that produce insulin. Some of the kids who had the infusion required less insulin and had better blood sugar control.

"It is very exciting," Desmond Schatz, M.D., a pediatric endocrinologist at The University of Florida in Gainesville, said. "I take care of children with diabetes all the time. I know what it is that they go through."

Barrett used to take 30 units of insulin a day. After the infusion he needs less than ten, and after two years of diabetes, his body is still producing some insulin.

"The results that we have experienced as a result of this study, in my mind are staggering," Brian Ross, Barrett's dad, said.

It's just one more way Barrett proves nothing can slow him down.

"Diabetes can't stop you from anything," Barrett declared.

Researchers hope cord blood infusions could one day become part of a standard treatment plan for kids with type 1 diabetes. A decade ago, less than one percent of Americans banked cord blood. Today that figure has grown to about four percent.

Heart Valves Fashioned From Stem Cells in Umbilical Cord Blood

They could grow with kids who are born with heart valve defects, researchers say

By Amanda Gardner, HealthDay Reporter



MONDAY, Nov. 10 (HealthDay News) — Stem cells collected at birth from the umbilical cord may help doctors fashion new heart valves for children born with heart valve defects.

The tissue-engineered valves would have the advantage of growing with the child, the German researchers said.

"If we replace a valve in a child, they will need surgery several times in their lifetime, because they will grow out of the devices, so the ultimate goal is to have a construct which is able to grow with the child and only have to do the surgery once," said study author Dr. Ralf Sodian, a cardiac surgeon at University Hospital of Munich. "Earlier is better, if it's possible."

Presenting Monday, November 10 at the American Heart Association's annual scientific sessions in New Orleans, Sodian reported that his team took stem cells from umbilical cord blood, stored them for 12 weeks, then seeded them on to eight heart valve scaffolds.

The stem cells went on to form a layer of tissue which included several characteristics of the "extracellular matrix," or the section of tissue outside of cells.

The engineered valves had almost 78 percent as much collagen as human tissue from pulmonary heart valves; 85 percent as much glycosaminoglycan as human tissue; and 67 percent as much elastin. Collagen and elastin are proteins in connective tissue, and glycosaminoglycan is a carbohydrate in connective tissue.

The valves also contained other proteins found in the human body.

"The whole idea of building a scaffold is a unique idea," said AHA spokesman Dr. Russell V. Luepker, the Mayo professor of epidemiology and community health at the University of Minnesota in Minneapolis. "We generally put progenitor cells in the heart and try to get them to grow muscle cells, and they're sitting in the middle of other cells."

"But to build a scaffold that looks like a heart valve then hope and anticipate that the cord blood cells will take that hint and differentiate, I think is very innovative," he added.

Still, the research is a long way from clinical practice.

"I don't think anyone has any idea if [these valves] would grow," Luepker said. "One may not know until it is put into a child, and the child grows. There are obviously a lot of hurdles to overcome."

Malfunctioning heart valves in babies that can't be surgically repaired are replaced with valves made from animal tissue, other human tissue or man-made materials.

Because these valves don't grow with the child, more surgeries for new valves are often needed.

There is also a possibility that the child's body will reject the artificial valve, although this is not so common, Luepker said.

A bigger issue is the sheer work that a heart valve has to perform. "The stresses on a heart valve are enormous," Luepker said. "They have to hold the blood back with each beat. The wear and tear on them which we see with metal and plastic valves is an issue, and those are fairly hard substances."

SOURCES: Ralf Sodian, M.D., cardiac surgeon, University Hospital of Munich, Germany; Russell V. Luepker, M.D., American Heart Association spokesman and Mayo professor, public health, department of epidemiology and community health, University of Minnesota, Minneapolis; Nov. 10, 2008, presentation, American Heart Association's annual scientific sessions, New Orleans

Copyright © 2008 ScoutNews LLC. All rights reserved.

Gardner, Amanda. "Heart Valves Fashioned From Stem Cells in Umbilical Cord Blood."

HealthDay 10 Nov. 2008

<http://www.healthday.com/Article.asp?AID=621200>

Cryo-Cell International, in compliance with AABB regulations, requires all cord blood collectors to be documented that they have read and understand, the proper techniques and procedures, of cord blood collection.

In order to comply with AABB regulations, please sign the last page of the cord blood collection instructions and return via the enclosed envelope or fax to 813-749-2253. Additional forms are accessible from our website: www.cryo-cell.com/company/request_forms.asp

The first 100 cord blood collectors that return their signed form will receive *Your Pregnancy*™ week by week for your practice. Please specify Spanish on the instructions if you wish to receive *Your Pregnancy* in Espanol.

***Only one copy of book per practice.**

STEP 3: LABELING & PREPARING FOR SHIPMENT

IF ANY QUESTIONS ARISE DURING THE COLLECTION PROCESS, CALL TOLL FREE (800) 764-7224 (24 HOURS, 7 DAYS A WEEK)

LABELING THE CORD BLOOD AND BIRTH MOTHER'S BLOOD

- ALL BLOOD TUBES AND THE CORD BLOOD COLLECTION BAGS MUST BE PROPERLY LABELED FOR PROCESSING.
- Pre-filled Parent and Neonate Labels are provided to identify the cord blood sample (Label #1) and each blood tube (2) of birth mother (Label #2, #3 & #4).
- Complete each specimen label with date, time and your initials. Attach a completed label to each tube (2).
- If LABELS ARE REPLACED, complete the Blue #3 Label included in the kit, or a hospital and/or mother's name and mother's local address.

PREPARING THE SPECIMENS FOR SHIPMENT

- Complete birth mother's Health History (Form 1) and Neonate and Part 2 of the Cord Blood Collection Form.
- Insert all 3 labeled birth mother's blood tubes into the provided plastic bag. Place the labeled parent blood bag with the attached label. Place the 3 tubes and cord blood bag into the large white zip bag and close the top seal on the bag.
- Place the address labeling from the large plastic zip bag front, inside the bag in bottom of the box to secure for shipping.
- Place clear tissue in the bottom and secure with tape.
- Place the completed Cord Blood Collection Form on top of the blue tissue and place both inside the provided shipping box.
- Insert two pre-filled Pre-filled Parental Neonate Label #1 into provided shipping box next to kit box.
- Parents should follow enclosed shipping instructions.
- The completed shipment should arrive at Cryo-Cell within 48 hours of collection.

IMPORTANT NOTICE:
 Reading this document and signing this form indicate you have read and understand the proper techniques and procedures of cord blood collecting with Cryo-Cell International.

Print Name: _____
 Signature: _____
 Practice Name: _____
 Practice Telephone Number: _____
 Date: _____

**REMOVE ALL SHARPS PRIOR TO SHIPMENT!
 SEND LABELED SPECIMENS ONLY**

