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Top of the News...

Stem Cells Discovered In Menstrual Blood

Oldsmar, Fla.-based cord blood bank Cryo-Cell said on November 1 that it has discovered a type of stem cell found in menstrual blood and has launched a service to enable women to collect and cryopreserve their menstrual stem cells.

The company said the stem cells in menstrual blood express multipotent markers of both adult and embryonic stem cells.



The menstrual stem cells multiply quickly and can differentiate into other types of cells, including heart, nerve, bone, cartilage and fat, according to early research.

The menstrual stem cells appear to have characteristics similar to those derived from the uterus (human endometrial stem cells), but they can be easily harvested in a non-invasive manner from menstrual fluid.

According to the company, this is the first time researchers have found an adult stem cell that is highly prolific and multipotent (able to differentiate into other cell types), and can also be easily harvested in a painless, non-invasive manner as compared to other stem cell sources such as bone marrow, fat or adult peripheral blood.

Several leading stem cell researchers have launched preclinical studies to evaluate the potential of these unique menstrual stem cells to treat heart disease, Type 1 diabetes and spinal cord injury.

The company said researchers believe that menstrual stem cells could someday be used to treat other serious illnesses, such as osteoporosis, stroke, Alzheimer's and Parkinson's disease, and that the cells may even be used for customized anti-aging or sports medicine treatments.

However, the company added, current research is very preliminary and it may take years to develop widely available clinical therapies.

Menstrual stem cells' unique properties, combined with their ease of collection and isolation, mean they could become a breakthrough source of multipotent cells.

The need for regenerative therapies incorporating cells that have the

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ability to engraft and differentiate is vast.

The ideal cell would also have the ability to be used in an allogeneic manner, meaning it could be used to treat others with whom there is a genetic match.

These cells appear to have all of these properties.

Cryo-Cell's new service, C'elle (pronounced "C-L"), allows women to collect and store menstrual stem cells in much the same way umbilical cord blood is preserved.

The specimen is transported to Cryo-Cell's laboratory for processing and cryopreservation.

Contact: <http://www.celle.com>

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Stem Cell Research News

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Distant Brain Signals Found To Regulate Neuron Maturation

Newly created neurons in adults rely on signals from distant brain regions to regulate their maturation and survival before they can communicate with existing neighboring cells, a finding that has important implications for the use of adult neural stem cells to replace brain cells lost by trauma or neurodegeneration, Yale School of Medicine (New Haven, Conn.) researchers report in *The Journal of Neuroscience*.

In fact, certain important synaptic connections, which is the circuitry that allows the brain cells to talk to each other, do not appear until 21 days after the birth of the new cells, according to Charles Greer, professor of neurosurgery and neurobiology, and senior author of the study.



Charles Greer

In the meantime, other areas of the brain provide information to the new cells, preventing them from disturbing ongoing functions until the cells are mature.

It was established in previous studies that several regions of the adult brain continue to generate new neurons, which are then integrated into existing brain circuitry.

However the mechanisms that allowed this to happen were not known.

To answer this question, Greer and Mary Whiteman, an M.D./Ph.D. candidate at Yale, studied how new neurons are integrated into the olfactory bulb that helps discriminate between odors, among other functions.

They found that new neurons continue to mature for six to eight weeks after they are first generated and that the new neurons receive input from higher brain regions for up to 10 days before they can make any outputs.

The other brain regions then continue to provide information to the new neurons as they integrate into existing networks.

The discovery of this previously unrecognized mechanism is significant, said Greer, because "if we want to use stem cells to replace neurons lost to injury or disease, we must ensure that they do not fire inappropriately, which could cause seizures or cognitive dysfunction."

Citation: *The Journal of Neuroscience* 27:

9951-9961 (October 2007)

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Therapies Only Need To Be 50 Percent Effective To Create Healthy Heart

A muscular dystrophy patient should be able to maintain a normal lifestyle if only 50 percent of the cells of the heart are healthy after stem cell or gene therapy, according to a study by University of Missouri-Columbia (Columbia, Mo.) researchers.

Heart disease is the leading cause of death in the United States and greatly affects the quality and length of life for individuals with specific forms of muscular dystrophy.

Recent discoveries have demonstrated that gene and/or stem cell therapy could help a variety of organs in the body, but until now scientists have been unsure whether the heart could benefit from these treatments.

Patients with Duchenne muscular dystrophy and Becker muscular dystrophy have a gene mutation that disrupts the production of a protein known as dystrophin.

Absence of this protein starts a chain reaction that eventually leads to muscle cell degeneration and death.

Eventually, the damaged muscle tissue is replaced by fibrous, bony or fatty tissue and loses function.

In the heart, this leads to severe heart disease and can place severe limitations on individuals afflicted with the disease.

In the past, scientists believed that the only way to have a healthy heart was to rid the heart of all damaged tissue.

The heart is considered to be a “synchronized organ;” therefore, it was believed that the heart needed to maintain 100 percent normal cells in order to stay healthy.

In gene therapy, mutated genes are replaced with healthy genes.

In stem cell therapy, diseased cells are replaced with healthy cells.

However, in these gene and stem cell therapies, it is not feasible to fix every cell in the heart.

Previously, scientists were uncertain whether

partial correction could benefit patients.

“In our study, we found that a heart with 50 percent normal cells looks like a normal heart,” said Dongsheng Duan, an associate professor of molecular microbiology and immunology at the MU School of Medicine. “More importantly, it acts like a normal heart. This is the first time that we have concrete evidence that partial gene or cell therapies will be effective for preventing heart disease in a mouse model of muscular dystrophy.”



Dongsheng Duan

“It’s important to note that this could improve the quality of life for individuals who have this heart condition,” said Brian Bostick, a doctoral student in molecular microbiology and immunology and the first author of the study. “We’re also looking at this as a possible way to prevent heart disease. If we can treat it early through gene therapy or cell therapy, we know now that it can be very beneficial for patients.”

The MU researchers said that this finding would have a positive impact on the ongoing gene and cell therapy studies in animal models of muscular dystrophy as well as in human patients.

It also raises the hope of developing effective gene and cell therapies for patients suffering from other heart diseases.

The story was published in *Circulation Research*, a journal of the American Heart Association.

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Discovery Of Development Signal Will Help Eye-Related Stem Cell Research

The discovery by British researchers of a crucial signal that switches on eye development will greatly assist researchers looking at stem cells connected to eye development, opening up an avenue of research that could eventually lead to an “eye in a dish.”

The scientists note, however, that an advancement of that scale is decades away.

A University of Warwick research team led

(Continued on page 4)

by Profs. Nick Dale and Elizabeth Jones from biological sciences department published their work October 25 in *Nature* in a paper entitled "Purine-mediated signaling triggers eye development."

The researchers were exploring whether release of an important signaling and energy carrying molecule known as ATP influenced the development of locomotion in frogs.

Their experiment introduced ectoenzyme molecules normally found on the outside surface of cells into frog embryos at one of the earliest stages when the frogs-to-be were just 8 cells in size.

Three ectoenzymes were used: E-NTPDase1, E-NTPDase2 and E-NTPDase3.

These degrade ATP following its release from cells.

However, each version of the molecule has slightly different effects on this degradation.

The Warwick research team's interest in locomotion was quickly eclipsed when they were amazed to find that the introduction of just one of the ectoenzymes (E-NTPDase2) had a dramatic affect on eye development in the tadpoles grown from these embryos.

When introduced in cells that would form the head area of the tadpole multiple eyes appeared to be created.

That was not the only surprise.

When it was introduced in some cells that formed body parts outside the head area it could still produce an additional "ectopic" eye leading to tadpoles with an additional eye in their side, abdomen or even along their tail.

E-NTPDase2 quickly latches on to ATP converting it to ADP.

This meant that where and when the researchers introduced E-NTPDase2 it led to nearby cells experiencing much higher levels of ADP.

The Warwick team hypothesized that ATP must be released in a short burst from the location where the eye will develop so that it can be converted to ADP by E-NTPDase2, thereby providing the trigger for eye development.

They were able to measure these short bursts of ATP using ATP sensors specially developed by Dale.

This is the first time researchers have been able to see and measure bursts of ATP so early in the development of living creatures.

The genes that initiate and direct eye development are well known and are collectively termed the Eye Field Transcription Factors" (EFTFs).

One of the mysteries of the field is how these

genes get turned on in the correct location and at the correct time to initiate eye development.

The Warwick research shows that this short burst of ATP followed by accumulation of ADP is a key signal for initiating expression of the EFTFs and hence the development of the eye.

The discovery of this surprising new signal that literally switches on eye development it is not restricted to frogs.

Mutations to the E-NTPDase2 gene on the human 9th chromosome is already known to cause severe head and eye defects.

This suggests that this newly discovered mechanism for triggering eye development applies across a wide range of species.

This new understanding of how eye development is triggered will greatly assist researchers exploring stem cells connected to eye development and opens up an avenue of a research that could in just a few decades lead to the ability to produce an "eye in a dish."

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Scientists Find Genes Regulating Embryonic Stem Cell Self-Renewal

Scientists in Singapore have identified two genes – Jmjd1a and Jmjd2c – that regulate self-renewal in embryonic stem cells.

The finding will have important ramifications for embryonic stem cell research, researchers said.

These are new pathways that the ES cell uses to counteract inappropriate silencing of key pluripotency genes.

Agitating these pathways affects the maintenance of ES cells," Ng said.

Embryonic stem cells (ES cells) are pluripotent.

They can differentiate into any of the specialized cell types of the body except the placenta, as well as new unspecialized stem cells, in a process known as "self-renewal."



Ng Huck Hui

(Continued on page 5)

Understanding the genetic basis of self-renewal is integral to the long-term maintenance of viable ES cell lines.

Dr. Ng Huck Hui and colleagues at the Genome Institute of Singapore investigated how modifications to chromatin structure influence gene transcription and ES cell function.

The researchers found that *Jmjd1a* and *Jmjd2c*, which encode enzymes that demethylate histone H3 lysine 9, regulate self-renewal in mouse ES cells.

Depletion of *Jmjd1a* and *Jmjd2c* promoted differentiation, at the expense of self-renewal.

Thus, these two histone modifying enzymes are required for maintaining pluripotency of ES cells.

The research is published in the October 15 issue of *Genes & Development*.

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Umbilical Cord Stem Cells Effective In Transplant, Regenerative Medicine

Two separate data abstracts displayed this week at the annual scientific meeting of the American Association of Blood Banks (AABB) highlight the increasing therapeutic use of autologous (one's own) cord blood stem cells for transplant and regenerative medicine, including treatments for blood and immune disorders, juvenile diabetes and neurological repair, according to the Cord Blood Registry.

One study analyzed four cases where an individual's own cord blood stem cells were released to treat aplastic anemia.

The cord blood was processed and stored at Cord Blood Registry and the transplants were conducted at three different institutions:

The cases suggest that autologous cord blood transplantation for aplastic anemia, a life-threatening disease with no known cause, is a safe and effective treatment protocol and demonstrate that this approach is amenable to use at different treatment centers across the United States.

The second report documented 13 cases of autologous cord blood stem cell use in both traditional and regenerative medicine applications.

In addition to the four cases of aplastic anemia (reviewed in detail in the first study), the report documented nine samples released for regenerative therapies:

– Two client samples were released for type 1 diabetes as part of an ongoing clinical trial at the University of Florida. Preliminary data from the first seven patients in the trial show the stem cell infusion appears to have reduced their

disease severity, possibly resetting the immune system and slowing the destruction of their insulin-producing cells.

– Six samples were released to treat neurological conditions, including cerebral palsy (four samples), anoxic brain injury (one sample), and traumatic brain injury (one sample). Although these six samples were not released as part of any specific clinical trial, anecdotal evidence by physicians involved with these cases suggests that the treatments were safe, with some anecdotal reports of improvement in quality of life. Since the study period ended, two more samples were released for treatment of cerebral palsy. The stem cell infusions were conducted at Duke University and Children's Memorial Hospital in Chicago.

– One additional sample was released for an experimental autologous stem cell infusion to treat a diagnosis of a rare immune disorder.

Cord Blood Registry (CBR) is the largest cord blood stem cell processing and cryopreservation service for familial use in transplantation and regenerative medicine and the most recommended cord blood bank by obstetricians.

Contact: <http://www.cordblood.com>

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Company Research

Stem Cell Treatment Reduces CLI Amputations

Harvest Technologies Corp., a privately-held biotech firm located in Plymouth, Mass., said on October 22 that a vascular medicine specialist has presented data from a clinical trial in which a bone marrow stem cell injection prevented leg amputation in more than half of the patients treated.



Berthold Amann, M.D., showed the results of 51 patients with end-stage peripheral arterial disease (PAD), so-called critical limb ischemia (CLI).

Nearly all of these patients had severe pain at rest and were already scheduled for leg amputation.

All surgical and endovascular options for these patients had been previously exhausted.

After the injection of a concentrate of the patients' own bone marrow stem cells, leg amputation could be avoided in more than half of these patients.

This is a major success because under normal circumstances, the amputation rate in CLI is 90-100 percent in this patient population within a year.

Injected autologous adult stem cell concentrates from bone marrow have been shown in international clinical studies to be significantly effective in achieving tissue regen-

(Continued on page 6)

eration in vascular, orthopedic and cardiac disease.

Until now, however, it has been difficult to process and concentrate a clinically significant dose of adult stem cells from a patient's bone marrow at the patient's hospital bedside in a simple, automated, 15-minute procedure.

The BMAC System from Harvest Technologies is the world's first and only technique that produces clinically significant amounts of adult stem and precursor cells from a small aspirate of autologous bone marrow in just 15 minutes.

For Amann's study ("Autologous Bone Marrow Transplantation for the Induction of Arteriogenesis: A New Treatment for Critical Limb Ischemia," conducted under his supervision at the Berlin (Germany) Vascular Center of Franziskus Hospital, the first 12 patients were treated using standard Ficoll separation that required 450-500 mls of bone marrow aspirate which yielded a concentrate of 1.08 billion cells.

Patients had to undergo general anesthesia, and procedure time was long at 385 minutes per patient.

He then treated 39 patients with the Harvest BMAC System.

With this rapid method, total procedure time per patient (i.e., anesthesia, aspiration, stem cell concentration and re-injection) was just 58 minutes per patient.

Less than half the amount of bone marrow aspirate (220 mls) was needed, and the Harvest BMAC stem cell concentrate had higher cell numbers than the Ficoll concentrate (3.36 billion bone marrow cells).

Even more important for the patient, there was no need for general anesthesia.

At Amann's follow-up of these study-patients at periods ranging from six months to three years, 30 of 51 patients demonstrated sufficient improvement in perfusion to avoid amputation.

Patients with limb salvage demonstrated an increase of critical physiological measurements: blood pressure at the ankle (ABI) and oxygen available to the foot tissue (transcutaneous oxygen).

Additionally, 16 of the 30 patients whose limbs were salvaged had complete healing of their ischemic wounds.

From a patient's view, it is even more important that several patients were able to walk again; walking distance was increased tenfold among the 30 patients whose limbs were salvaged.

Based upon these positive results, Amann has undertaken a further study to establish stem cell therapy in the treatment of patients with severe peripheral arterial disease with critical limb ischemia.

This study will include 90 patients in a randomized, placebo-controlled, double-blind study using Harvest BMAC(TM).

The FDA has granted Investigational Device Exemption (IDE) approval to Harvest to launch a 48-patient "feasibility" clinical trial in the United States using the company's BMAC System to treat patients with CLI.

The BMAC System is a point-of-care device for

concentrating bone marrow stem cells in approximately 15 minutes.

The study's design provides for injecting a patient's own bone marrow stem cells into the affected limb to reduce the potential for limb amputation.

It is believed that the injection of stem cells will induce the growth of new arteries and so arrest and possibly improve the effects of CLI. Patients who are being enrolled in this study have exhausted all other surgical options and are at extreme risk for major amputation.

This U.S. clinical study is being led by principal investigator Mark D. Iafrati, M.D., chief of vascular surgery at Tufts-New England Medical Center, Boston.

Five additional major university-based medical centers are participating.

Contact: <http://www.harvesttech.com>

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Study Using Pluristem Cells Shows Promise As Treatment For Stroke

New York, N.Y.-based Pluristem Life Systems, Inc. (PLRS), said on October 18 that results from a German study using Pluristem's PLacenta eXpanded (PLX) cells in treating ischemic stroke showed initial promise as a potential therapy to treat stroke victims.

Ischemic stroke accounts for approximately 90 percent of all stroke cases and is caused when an artery to the brain becomes blocked causing a sudden disruption of blood flow.

Current estimates suggest ischemic stroke affects approximately two million patients annually worldwide with a large percentage dying or becoming permanently disabled.

PLX cells are mesenchymal stem cells (MSCs) obtained from the placenta and expanded using Pluristem's proprietary 3D PluriX technology.

Fraunhofer Institute's (Leipzig, Germany) scientists systemically injected PLX cells into spontaneously hypertensive rats that had undergone middle cerebral artery occlusion, a commonly accepted ischemic stroke model.

At the current stage, this animal trial shows a significant advantage in functional recovery over a control group that did not receive PLX cells.

"We are very excited about the results and believe that utilizing our PLX product may successfully treat millions of ischemic stroke patients and lead to a multi-billion dollar market," said CEO Zami Aberman. "This independent study, together with the previously announced favorable pre-clinical results of PLX cells to treat limb ischemia and Parkinson's disease, give us a robust pipe line for developing new therapeutic products following the foreseeable submission of the IND for treatment of blood cancers."

The trial is conducted under the supervision of Prof.

(Continued on page 7)

Frank Emmrich, head of the Fraunhofer Institute for Cell Therapy and Immunology (IZI), a branch of the Fraunhofer Society.

“PLX cells show potential to become a treatment to functionally recover from a stroke,” Emmrich said. “However, the preliminary findings have to be confirmed and the running experimental series have to be completed before a final statement can be made. Additional optimization surrounding the administration of PLX cells will be required to supply clear evidence that PLX cells may help patients with ischemic stroke.”

Pluristem is presenting results of pre-clinical studies of its PLX cells at the “3rd World Congress on Regenerative Medicine” in Leipzig.

Pluristem is developing non-personalized (allogeneic) stem cell therapy products for the treatment of numerous severe degenerative, malignant and autoimmune disorders.

Pluristem has offices in the USA with research and manufacturing facilities in Israel.

Contact: <http://www.pluristem.com>

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Positive Results From Stem Cell Therapy For Bone Fracture Trial

Ann Arbor, Mich.-based Aastrom Biosciences, Inc. (ASTM) said on October 18 that a Phase I/II clinical trial using its bone repair cells showed an overall healing rate of 91 percent after one year among patients with fractures that had failed to heal after one or more medical procedures.

Final results of the study were presented today by Matthew L. Jimenez, M.D., of the Illinois Bone & Joint Institute, during a podium presentation at the Orthopaedic Trauma Association annual meeting in Boston, Mass.

The study was designed to collect safety and efficacy data utilizing bone repair cells (BRCs) in the treatment of severe non-union tibia, humerus or femur fractures.

Thirty-six eligible patients with severe long bone non-union fractures of the tibia, humerus or femur, that had failed to heal with one or more (average of 1.75) prior medical procedures, were enrolled in the multi-center, prospective, open-label clinical trial and treated with BRCs.

Overall, 34 patients completed six-month post-treatment follow-up and 33 completed 12-month follow-up.

The 33 patients followed for 12 months showed an overall healing rate of 91 percent, as determined by bone bridging observed with radiographic imaging or computed tomography.

Final results showed healing success in 91 percent (21 of 23) of tibia fractures, 100 percent (3 of 3) of humerus fractures, and 86 percent (6 of 7) of femur fractures.

In addition to the 91 percent healing rate observed after 12 months, results at six months showed that bone

bridging successfully occurred in 85 percent (29 of 34) of patients and that signs of early healing (callus formation) were present in 97 percent (33 of 34) of patients.

Three patients failed to complete the required follow-up visits.

Though final data could not be collected from these three patients, two showed healing by 18 weeks.

No cell-related adverse events were reported.

“The results suggest that BRCs are efficacious for the treatment of recalcitrant long bone non-union fractures,” said Jimenez, the lead investigator for the study. “BRCs have the potential to become a powerful new tool for bone regeneration and to improve the management of severe fractures.”

BRCs are derived from a small sample of the patient’s bone marrow that is processed using Aastrom’s tissue repair cell (TRC) technology to generate larger numbers of stem and early progenitor cells with enhanced therapeutic potential.

In the study, patients underwent a standard open reduction and internal fixation surgery in which BRCs were applied directly to the fracture site, together with an allograft bone matrix, to promote local bone regeneration.

“The positive results from this study, along with early clinical data reported from osteonecrosis patients two weeks ago, further supports the broad application of our proprietary TRC Technology in the field of orthopedics,” said CEO George Dunbar.

In addition to bone regeneration, Aastrom is currently developing TRC-based therapies for vascular, cardiac and neural tissue regeneration applications.

The company recently reported positive early data from a German study evaluating the use of BRCs to treat patients suffering from osteonecrosis of the femoral head.

Also reported were positive interim results from a German Phase I/II trial utilizing vascular repair cells (VRCs) to treat diabetic patients with critical limb ischemia (CLI), the most severe form of peripheral arterial disease.

Aastrom is developing autologous cell products for the repair or regeneration of human tissue.

Contact: <http://www.aastrom.com>

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Trial Evaluates SC Treatment For Juvenile Diabetes

Columbia, Md.-based Osiris Therapeutics, Inc. (OSIR) said on October 25 that it has launched a Phase II clinical trial evaluating a stem cell therapy as a treatment for type 1, or juvenile, diabetes.

Through a partnership with the Juvenile Diabetes Research Foundation (JDRF), the organization has provided \$4 million in funding to support the development of the company’s Prochymal product as a treatment for the preservation of insulin production in patients with newly diagnosed type 1

(Continued on page 8)

diabetes mellitus.

Prochymal is a preparation of mesenchymal stem cells specially formulated for intravenous infusion.

The stem cells are obtained from the bone marrow of healthy adult donors.

Type 1 diabetes, commonly known as juvenile diabetes or insulin-dependent diabetes, is an autoimmune disorder that attacks and destroys insulin producing islet cells in the pancreas causing glucose accumulation in the blood.

As a result, those suffering from type 1 diabetes must take insulin to regulate blood sugar levels.



Over time, poorly controlled diabetes can lead to serious health conditions, including heart disease, stroke, blindness, amputations, kidney disease and nerve damage.

Currently, there are no preventative measures for type 1 diabetes.

In preclinical research, both animal and human bone marrow-derived mesenchymal stem cells (MSCs) were shown to preserve beta cell function in animal models of diabetes.

“A critical unmet need in the treatment of type 1 diabetes, which currently affects as many as 3 million peo-

ple in the country, is addressing the autoimmune attack that causes the disease,” said JDRD research chief Richard Insel, M.D.

This marks the fifth indication for which the therapy has been granted approval to proceed into the clinical stages of testing.

The FDA recently cleared the company to begin a Phase III clinical trial evaluating Prochymal as a treatment for acute graft versus host disease (GVHD), a life threatening reaction of the immune system for which there is no treatment.

In the Phase II trial for acute GVHD, Prochymal was well tolerated and demonstrated a 77 percent complete remission rate.

The Phase II trial will evaluate the safety and efficacy of Prochymal in conjunction with standard of care in preserving insulin production in patients recently diagnosed with type 1 diabetes mellitus.

Cell mediated inflammatory diseases result in high levels of pro-inflammatory chemical signals called cytokines.

These cytokines cause the unbalanced activation of certain immune cells that result in tissue damage.

Delivered intravenously, Prochymal is able to target areas of active inflammation.

Published data indicate that Prochymal is able to down-regulate the production of pro-inflammatory cytokines, including tumor necrosis factor-alpha or TNF-alpha and interferon-gamma.

Contact: <http://www.Osiris.com>

Stem Cell Business News

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