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**Happy New Year  
from  
Transplant News**

## **First face transplant, Internet solicitation for donors, fabricated stem cell data major news events in 2005**

*By Jim Warren*

*Editor & Publisher*

The year in transplantation 2005 will long be remembered as a year of medical firsts, the Internet became a primary instrument in seeking a life saving organ, and the tragic fall of the world's most prolific, well-known embryonic stem cell researcher.

The most anticipated transplant occurred in late November when a French team of surgeons, led by transplant pioneer Jean-Michel Dubernard, MD, performed the world's first partial face transplant. Earlier in the year an Alabama woman became the first previously infertile woman with an ovary transplant to give birth. In October, Israeli scientists reported successfully transplanting previously frozen whole ovaries in sheep.

In June the United Network for Organ Sharing (UNOS) surprisingly called off plans to compete with existing online registries like MatchingDonors.com and develop its own Web site to list patients in need of a kidney transplant or individuals considering live donation. UNOS decided they could best serve the transplant community by developing a site where individuals considering live donation or using an online registry can go to get accurate, unbiased information.

Finally, in December, South Korean embryonic stem cell researcher Hwang Woo-suk admitted his data on creating 11 embryonic stem cell lines tailored to individual patients had been fabricated. The spotlight now falls on other claims by Hwang including having created the world's first cloned dog.

On a brighter note the Organ Procurement and Transplantation Network (OPTN) reported a record 26,984 Americans received a solid organ transplant in 2004, a 6% increase over 2003. And for the first time in four years, the deceased donors outnumbered organs from live donors. Much credit is given to the Health Resources and Services Administration (HRSA) Breakthrough Organ Donation Collaborative. The collaborative, now in its third year, honored 184 US hospitals for achieving a 75% organ donor rate and set a new goal of ending all deaths on the waiting list in the next 10 years.

Here is the year 2005 in review.

### **JANUARY**

•The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issues revised organ procurement rules for hospitals and critical access hospitals. Beginning in July the respective hospitals will be required to measure the effectiveness of their organ procurement efforts using

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## Hwang finally admits embryonic stem cell data in *Science* was fabricated

After several weeks of fending off charges about the validity of his data, South Korean stem cell researcher Hwang Woo Suk finally admitted he had fabricated the results of all 11 stem cell lines he claimed were tailored for individual patients.

The findings were announced by a Seoul National University investigative panel, which announced in mid-December that nine of the 11 cell lines were fabricated. Hwang finally admitted on December 28 that all 11 that were announced in *Science* magazine were fake.

“The panel couldn’t find stem cells that match patients’ DNA regarding the 2005 paper (in *Science*) and it believes that Hwang’s team doesn’t have scientific

data to prove [that such stem cells] were made” Roe Jung-hye, the university’s dean of research affairs, said, the *Wall Street Journal* reported.

Roe said the panel found the stem cells Hwang claimed to have established in 2005 actually came from fertilized eggs and weren’t designed specifically for patients.

The university panel is now turning its sights on Hwang’s other research. The panel is asking for DNA tests on his seminal work on a dog clone named Snuppy, and other trials he conducted in 2004 and 2005.

Hwang’s troubles now turn the spotlight back on his US collaborator Gerald Schatten, the University of Pittsburgh stem cell researcher who was co-author of the original paper in *Science*.

Schatten broke off with Hwang in November after learning he had lied about paying for eggs obtained in his early experiments.

Both Hwang and Schatten have asked *Science* magazine to retract the paper, but editors have remained adamant that all 25 authors must make the request. In light of the new developments, the editors are indicating their willingness to move forward with a retraction unless the authors respond “in a timely manner,” the *Pittsburgh Gazette* reported.

The University of Pittsburgh has named a panel of six scientists to make recommendations to Arthur Levine, senior vice chancellor for health sciences, on Schatten’s role in the fabricated research results.

Schatten, a reproductive biologist who directs the Pittsburgh Development Center at Magee-Womens Research Institute, was a co-author on both this year’s disputed *Science* article, and the dog-cloning study. However, he has maintained he didn’t actually perform any of the research and served primarily as an advisor on preparing for publication of the results, according to the *Gazette*.

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## Year 2005 in Review

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conversion rate data determined by the number of actual donors over the number of eligible donors as defined by their local organ procurement organization (OPO)

- Mike Leavitt is unanimously confirmed by the US Senate as Secretary of Health and Human Services.

- Almost a year after a body parts selling scheme forced the suspension of its willed body program, University of California at Los Angeles medical school officials announce their solution to prevent such abuses in the future. Under the new plan, all UC medical schools will be required to implant barcodes or radio-frequency identifiers in cadavers, and video cameras must be installed at loading docks to monitor after-hours activities involving the cadavers.

- The Health Resources and Services Administration (HRSA) awards \$4.3 million in grants to projects designed to increase organ and tissue donation. The grants to 15 organizations will test the effectiveness of social and behavioral, clinical, and media-based interventions to increase the number of donors.

- California stem cell institute mandated by voters in November 2004 takes its first steps towards launching the \$3 billion program. The California Institute for Regenerative Medicine will be governed by a 29-member oversight committee.

- Texas woman pays \$50,000 for "Little Nicky," the world's first cloned kitty-on-order.

- Australia issues five-year ban on conducting xenotransplantation trials using humans.

### FEBRUARY

- The Department of Health and Human Services (HHS) Centers for Medicare and Medicaid (CMS) issues three sets of new rules that will impact organ and tissue procurement and transplantation practices for the foreseeable future once they are implemented. They include: *Proposed Rule on Conditions of Coverage for Organ Procurement Organizations*; *Proposed Conditions: Requirements for Approval and Re-Approval of Transplant Centers*; and *Proposed Rules for End Stage Renal Disease Programs*.

The OPO rules propose changing emphasis from how many procedures are performed to focus on how well OPOs perform each of their mandated tasks. "The changes ensure that each OPO utilizes best practices to improve efficiency, effectiveness and quality," the rule states. "Our overall goal is to improve the functioning of poor performing OPOs, rather than to simply terminate them."

The transplant center regulations place new emphasis on a transplant center's ability to perform successful organ transplants using state of the art practices to ensure the safety of both recipients and living donors. "These new requirements are a key element in our multilevel approach to increasing organ, tissue and bone marrow donation and assuring the highest quality of care for Medicare beneficiaries who need transplants," said CMS Administrator Mark McClellan, MD.

The proposed ESRD program rules, the first changes in 40-years, emphasize that more comprehensive dialysis patient assessments be conducted, including the patient's suitability to be referred for a transplant and criteria to identify potentially unstable patients.

The transplant community is given 60-days to comment on the OPO and transplant center regs, and 90-days on the ESRD regs.

- Lester Crawford to be nominated by President Bush to become commissioner of the US Food and Drug Administration (FDA).

- Paul Lacy, one of the early pioneers in islet cell transplantation, passes away on Feb. 15 at the age of 81.

- Three German transplant recipients are suspected of contracting rabies from the same donor. Three other recipients who received organs from same donor are not infected, however.

- South Korean scientists, led by Professor Hwang Woo-suk of Seoul National University, are given approval by the Korean government to continue stem cell research under strict guidelines established by the Ministry of Health. Hwang reported they successfully cloned a human embryo from which they collected stem cells, in February 2004.

### MARCH

- A record 26,984 Americans received a solid organ transplant in 2004, according to preliminary data released by the Organ Procurement and Transplantation Network (OPTN). The record, a 6% increase over 2003, was fueled by an almost 11% increase in the number of deceased organ donors over 2003, and was the second highest annual increase since national record keeping began in 1987. In addition, it was the first time in four years that the number of deceased donors topped the number of live donors.

- The death rate for patients awaiting liver transplants is down and the use of expanded criteria donor (ECD) kidneys in transplantation is increasing steadily, according to a new HRSA report. The number of donors after cardiac death (DCD) has also been growing, from 57 in 1994 to 189 in 2002, to 271 in 2003.

(Continued on page 4)

- Bi-partisan-backed legislation which would increase federal support for embryonic stem cell research is introduced in the US Senate with broad support. Similar legislation died in Congress last year.

- Bill establishing a national cord blood stem cell bank is introduced in the House of Representatives. The bill would establish a national network to prepare, store, and distribute human umbilical cord blood stem cells for the treatment of patients and support peer-review research of cord blood cells.

- CMS extends comment period for OPO and transplant center rules 60 days; due date is now June 6.

- Transplant pioneer Hans Sollinger, MD, chairman of the Division of Transplantation at the University of Wisconsin Medical School, is appointed chair of the Secretary's Advisory Committee on Organ Transplantation (ACOT).

- After 30 years on the job, both Bernard Cohen, PhD, and Guido Persign, MD, director and medical director respectively, of the Eurotransplant Foundation in Leiden, The Netherlands, announce they will leave the organization together on Sept. 1.

- Two of the three organ transplant recipients in Germany who contracted rabies from an infected donor pass away. The third infected patient remains in serious condition.

#### **APRIL**

- A bipartisan group of Senators led by Senate Majority Leader Bill Frist (R-TN) and Christopher Dodd (D-CT) launch a campaign to get the Organ Donation and Recovery Improvement Act (PL -108-216) fully funded in 2006. The bill contains \$25 million for FY 2005 to spend on such programs as reimbursing living organ donors, funding new organ procurement positions for hospitals, and increasing research efforts to improve the recovery of organs.

- Institute of Medicine calls for establishment of a national network to oversee the storage and use of umbilical cord blood. The IOM report recommended a goal of banking 100,000 units to increase the odds of finding good genetic matches.

- California's organ/tissue donor registry is finally launched; more than 25,000 sign-up in first 10 days.

- Todd Krampitz, the Texas man who created a national controversy in 2004 by receiving a liver transplant after conducting a media blitz asking for a directed donation, dies.

- The Transplantation Society adopts international standards of care for live donors.

- International Society for Heart and Lung

Transplantation (ISHLT) announces it will begin a review of the process for prioritizing heart and lung transplant candidates and the treatments they receive.

#### **MAY**

- More than 100 participants meet for two days in Philadelphia to come up with a plan for expanding the practice of donation after cardiac death (DCD) in the continuum of quality end-of-life care. The group produces a template of recommendations aimed at getting the transplant community to agree there is a "societal responsibility that regularly enables organ transplantation from deceased donors, determined to be dead by either circulatory or brain criteria."

- UNOS announces it will hold a one-day public hearing in June on developing a distinct Web site to assist patients in need of a kidney transplant and individuals considering live donation. ACOT supports development of the Web site and calls on Secretary Leavitt to press the OPTN to develop an online registry.

- A National Academies panel issues ethical guidelines for embryonic stem cell researchers to follow. With the US government deadlocked over expanding its oversight of stem cell research policies, the academy says the guidelines are intended to enhance the integrity of privately funded human embryonic stem cell research and encourage responsible practices.

- \*House members join Senate colleagues in seeking to get the Organ Recovery and Improvement Act of 2006 fully funded. Bipartisan effort is led by Reps. Michael Bilirakis (R-FL), vice chairman of the House Energy and Commerce Committee, and Jay Inslee (D-WA).

- Louisville, KY, selected by the National Kidney Foundation (NKF) to host the 2006 US Transplant Games on June 16-21, 2006.

- World Health Organization (WHO) urges member states to conduct strict oversight of xenotransplantation research. Member states are urged to implement a 2004 resolution which calls to allow xenotransplantation "only when effective national regulatory control and surveillance mechanisms overseen by National Health Authorities are in place."

#### **JUNE**

- In a surprising about face, UNOS announces it will not develop a Web site listing patients in need of a kidney transplant and individuals considering live kidney donation. The decision not to complete with other online registries such as Matchingdonors.com and livingdonorsonline.com is recommended by the OPTN/UNOS Ad Hoc Committee on Public

Solicitation of Organs, following a one-day fact finding hearing in Chicago.

- At least six organ transplant recipients in the US have died after being infected with lymphocytic choriomeningitis virus (LCMV), a virus rarely found in humans, transmitted by rodents such as hamsters and mice, according to the Centers for Disease Control and Prevention (CDC). The report is issued after three out of four people in New England die receiving organs from a woman infected with LCMV.

- For the first time ever, a previously infertile woman who was transplanted with an ovary from her identical twin sister gives birth. Stephanie Yarber, 25, of Muscle Shoals, AL, gave birth on June 13<sup>th</sup> to a healthy baby girl.

- Legislation providing a tax credit for living organ donors introduced in the House of Representatives. The bill, introduced by Rep. Joe Wilson (R-SC), would give living organ donors a one-time tax credit of up to \$5,000 to help cover personal expenses.

- A South Korean research team led by Hwang Woo-suk reports they have successfully created nearly a dozen cloned human embryos that are genetic twins of patients with various medical problems and isolated from the embryos batches of stem cells with the potential to replace failing tissues on those patients. The report is hailed as a major breakthrough in therapeutic cloning.

- FDA panel narrowly rejects Abiomed's request for a Humanitarian Device Exemption (HDE) to market its AbioCor total artificial heart.

## **JULY**

- Attempts to get full funding in FY 2006 continue in both the House and Senate. The month ends with a bipartisan effort led by Senators Frist (R-TN) and Dodd (D-CT) to get full funding when the appropriations committee goes to conference in the fall.

- With the goal of getting the largest hospitals in the US to achieve organ donation rates of 75% or more on the way to being successful, the HRSA's Organ Donation Breakthrough Collaborative sets its sights on an even more ambitious goal – reducing the number of people who die while waiting for an organ to zero. To achieve this goal, the Collaborative challenges hospitals to increase the mean number of recipients transplanted per donor from 3.06, the 2004 mean, to 3.75 or higher.

- The Division of Transplantation announces that in the first five months of this year organ donation is up 9.5% over the first five months of 2004.

- Bi-partisan group of Senators urge the Government Accountability Office (GAO) to study pediatric kidney transplant coverage policies. Current policy only covers

follow-up care for 36 months after transplant which may lead to early rejection, they tell GAO.

- Illinois becomes the 43<sup>rd</sup> state in the US to pass first person consent legislation making it impossible for a family member to overrule an individual's documented wish to be an organ/tissue donor. Only 7 states in the US now lack first person consent laws: Alabama, Georgia, Massachusetts, Mississippi, New Hampshire, New York, and Texas.

- Lester Crawford confirmed to head the FDA.

## **AUGUST**

- Sen. Frist (R-TN) announces he is breaking with President Bush's embryonic stem cell funding policy and now favors expanding federal funding.

- Joint Commission announces it will launch a Certification Program for Organ Transplant Centers in 2006 to help US transplant centers meet new requirements mandated by the CMS.

- More than 100,000 Californians join online organ/tissue donor registry in first four months.

- University of Pittsburgh Medical School researchers receive FDA approval to conduct trial to determine the safety, feasibility of injecting a patient's own bone marrow-derived stem cells into the heart during conventional heart bypass surgery.

- South Korean embryonic stem cell researcher Hwang Woo-suk announces he and colleagues have successfully cloned the first dog.

- European transplant organizations and the World Health Organization announce the first World Day for Organ Donation and Transplantation will be observed on Oct. 14 under the patronage of the Council of Europe.

## **SEPTEMBER**

- Hurricane Katrina creates havoc for organ transplant candidates, dialysis patients and the medical community in general in Louisiana, Mississippi and Alabama. The Louisiana Organ Procurement Organization (LOPA) offices continues to operate despite a majority of the staff displaced and phone and Internet communications in shambles. All major national transplant organizations announce efforts to assure that transplant patients and candidates on the waitlist for an organ will have access to medications and support from the nation's organ procurement organizations.

- A broad group of private companies, public agencies and national organizations develop an online service for authorized health professionals to gain electronic access to victims of Hurricane Katrina prescription medication records.

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- Scramble for signing-up millions of Medicare-eligible Americans for Medicare Prescription Drug Plans (PDPs) begins with the release of companies approved in each state. The PDPs can begin marketing their Part D plans on Oct. 1.

- The St. Vincent Medical Center liver transplant program in Los Angeles is suspended after an official finds a Saudi national was improperly moved to top of waiting list. The patient was 52<sup>nd</sup> on the waiting list. In addition, the Saudi Embassy paid St. Vincent \$339,000 for the transplant, about 25% more than would normally be paid by private insurers.

- The Securities and Exchange Commission (SEC) announces it is conducting an inquiry into Senate Majority Leader Bill Frist's (R-TN) sale of all his holdings in Hospital Corporation of America, which was founded by his father and brother.

- After just two months on the job, Lester Crawford abruptly resigns as commission of FDA. Reports cite financial irregularities as the reason. Andrew Von Eschenbach, MD, currently director of the National Cancer Institute, named acting commissioner.

- Bernard Cohen, PhD, and Guido Persign, MD, officially step down from Eurotransplant leadership roles. The "Eurotransplant Twins" are replaced by three new directors – Arie Oosterlee, General Director; Axel Rahmel, MD, Medical Director; and Wim van Zwet, Director of Finance and IT.

## **OCTOBER**

- To the surprise of absolutely no one, the UNOS is selected by the HRSA to administer the OPTN. The new seven year contract consists of two years guaranteed, and five "option years." The estimated value of the contract for the full seven years is \$198 million.

- After years of increases of 5% to 10%, the rate for Americans experiencing kidney failure rates have finally stabilized, according to new research conducted by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. However, the study finds that "persistent" racial disparities remain.

- Biomedical Tissue Services (BTS), a New Jersey-based tissue recovery company, being investigated by the Brooklyn, NY district attorney for illegally procuring tissues from unscreened corpses in New York funeral homes. The *New York Daily News* reports the company procured bones, tissues and other body parts from at least six funeral homes without the knowledge of relatives and provided them to tissue processing firms using false documentation. The FDA announces it has

begun an investigation of the human tissue recovered by BTS.

- UCLA Willed Body Program, shut down 18 months ago after alleged body parts selling scheme, given ok to reopen soon.

- NKF announces more than 100 experts from around the world will convene in Lisbon, Portugal Feb. 2-4, 2006 to develop global guidelines for improving outcomes for people receiving kidney transplants.

- Israeli scientists report they successfully transplanted previously frozen whole ovaries in sheep.

- First ever multicenter trial comparing machine-perfused cadaveric kidneys to cold storage to begin Nov. 1 in The Netherlands, German and Belgium. The study will be conducted under the auspices of a Scientific Steering Committee and the European International Transplant Foundation in Leiden, The Netherlands.

## **NOVEMBER**

- OPTN strategic planning committee begins most ambitious overhaul of US transplant system since it was established 20 years ago. The goals include increasing the number of transplants performed, beefing up oversight of the huge proliferation of live donors, implementing "net benefit" as a tool in the allocation of organs, and reducing disparities in who gets an organ.

- Following reports that more than 30 patients died over the past two years on the waitlist for a liver transplant, the University of California, Irvine (UCI) shuts down liver transplant program. The story is broken by the *Los Angeles Times* after it requested a CMS report through the Freedom of Information Act.

- St. Vincent closes its liver transplant program.

- Responding to the UCI and St. Vincent medical center organ allocation scandals, the OPTN/UNOS board of directors approves establishment of a subcommittee to develop recommendations for proactively uncovering problems before they become major problems. The subcommittee will discuss organ turn-down rates, requiring onsite availability and establishing a "whistleblower provision."

- New heart allocation scheme approved by OPTN/UNOS board. Hearts will be offered to candidates in the two highest levels of medical urgency status up to a distance of 500 miles from the donor hospital before any local candidates of lower urgency would be eligible to receive the offer of an organ.

- Korean stem cell pioneer Hwang Woo-suk admits possibility that hundreds of eggs had been bought for his research from junior scientists in his laboratory at Seoul National University. Breach in ethics causes

## President Bush signs bill creating a national cord blood program

Legislation creating a national cord blood program with federal funding was signed into law by President Bush on Dec. 20.

The Stem Cell Therapeutic and Research Act of 2005 (H.R. 2520) establishes a national umbilical cord blood program providing federal funding to collect and store cord blood for life-saving blood cell transplants and reauthorizes the existing national marrow donor registry administered by the National Marrow Donor Program (NMDP).

The combined program – which will be named the C.W. Bill Young Cell Transplantation Program – will have \$79 million in federal funding to increase the number of cord blood units available for matches. The NMDP said in a press release that the goal is to provide an additional 150,000 cord blood units for public use and establish a system that allows transplant physicians access to adult volunteer donors and cord blood units.

“The creation of a national umbilical cord blood program significantly improves access for patients in need of transplants to treat blood diseases, metabolic and other rare disorders,” said Joanne Kurtzberg, MD,

University

### Year in Review 2005

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of Pittsburgh stem cell researcher Gerald Schatten to end his collaboration with Hwang.

### DECEMBER

\*The race to perform the world’s first partial face transplant is won by French surgeons. A surgical team, led by transplant pioneer Jean-Michel Dubernard, MD, grafted the nose, chin and lips from a brain dead woman donor, on the face of 38-year-old Isabelle Dinoire. The surgery took place in Amiens, a city in northern France.

•In a stunning reversal Hwang Woo-suk admits all 11 stem cell lines he claimed were tailored for individual patients had been fabricated. The findings were announced by a Seoul National University investigative panel which initially found that nine of the 11 cells lines were fabricated. The panel is now investigating Hwang’s claim he successfully cloned the first dog.

•President Bush signs law creating nation’s first National Cord Blood Registry.

•FDA approves first test to screen for West Nile Virus (WNV) in organ, tissue, cell and blood donors. The test will be marketed by the Chiron Corporation.

founder and director of the Center for Cord Blood at NMDP and medical director of the Duke University Pediatric Bone Marrow Program. “The national program also holds great promise and potential to treat other blood diseases not currently being treated by transplants.”

Representatives Mike Castle (R-DE) and Diana DeGette (D-CO), co-sponsors of the bill in the House, praised the passage of the legislation but emphasized it is not a replacement for passing legislation expanding embryonic stem cell research.

“I believe the passage of this stem cell legislation is certainly a step in the right direction, but today’s bill is in no way a substitution for the potential advancement provided for in H.R. 810 – The Stem Cell Research Enhancement Act of 2005 –which has the backing of many medical groups, leading scientists, several research universities and public advocacy groups,” Castle said in a press release. “Umbilical cords are adult stem cells, and while valuable for certain blood-related diseases, they are difficult to harvest and grow and do not exist for every tissue type. On the other hand, embryonic stem cells have potential to grow into any type of cell in the body, are easier to identify, isolate, purify and capable of continual reproduction.”

DeGette noted cord blood cells have been effective in treating blood-related diseases like sickle-cell anemia, but said the House has just taken the first step towards finding cures for diseases, which affect millions of Americans.

The bill, which was written by Rep. Chris Smith (R-NJ), passed the House of Representatives in May by a vote of 431-1.

“Cord blood stem cells are already treating patients and now, for the first time ever, my bill establishes a nationwide stem cell transplantation system once it becomes law,” Smith said.

The C.W. Bill Young Cell Transplantation Program is the successor to the NMDP’s National Bone Marrow Donor Registry. The bill allows the Secretary of Health and Human Services (HHS) to award separate contracts to perform each of the major functions of the program “if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interests of patients.” The Secretary will also establish a council to advise him on the program.

A spokesman for the NMDP told *Transplant News* the program intends on bidding to manage the cord blood and marrow registries, but not on becoming a cord blood bank.

## Business Briefs

### **Astellas Pharma files NDA with FDA for modified release formulation of FK506**

Astellas Pharma US, Inc., Deerfield, IL, has submitted a New Drug Applications (NDA) to the US Food and Drug Administration (FDA) for its immunosuppressive FK506 modified release formulation (tacrolimus) with the target indication for preventing the rejection of transplanted organs.

The company says FK506 modified release formulation is a modified release version of Prograf (tacrolimus) that can be administered once daily instead of the conventional twice daily. Astellas believes patient compliance will improve by having to take a drug just once a day, which will lead to better long term graft survival.

In addition, the formulation is expected to be at least as safe as the conventional formulation since the peak blood concentration can be controlled at lower levels and dosage based on blood concentrations can be optimized.

An application for regulatory approval in Europe of FK506 modified release formulation is currently being prepared and Phase II trials are underway in Japan

Contact: Web site: [www.astellas.com](http://www.astellas.com)

### **Osiris cleared by FDA to begin Phase II stem cell trial for the treatment of Crohn's Disease**

Osiris Therapeutics, Inc., Baltimore, MD, announced it has received clearance from the FDA to begin enrollment in a Phase II clinical trial to evaluate the safety and effectiveness of Prochymal for the treatment of Crohn's Disease. When the program is launched, Osiris will have five active clinical trials evaluating its proprietary stem cell drugs in autoimmune, oncology, cardiac and orthopedic indications.

In the trial, Prochymal is being evaluated for its ability to reduce inflammation and repair of damaged tissue. The company says studies have shown that the type of stem cell used in Prochymal, the mesenchymal stem cell or MSC, can specifically target areas of inflammation.

Osiris received clearance to proceed into the Phase II trial after submitting an IND application to FDA for the treatment of inflammatory bowel diseases, including Crohn's.

Contact: Web site: [www.OsirisTx.com](http://www.OsirisTx.com)

### **Y's Therapeutics begins Phase II trial to evaluate YSPSL in prevention of delayed graft function**

Y's Therapeutics Co., Ltd., Tokyo, Japan, a privately held biopharmaceutical company, has initiated a Phase II clinical trial for YSPSL for the prevention of delayed graft function (DGF) in patients undergoing cadaveric kidney transplantation. The company says YSPSL is a recombinant molecule resulting from the fusion of P-selectin glycoprotein ligand (PSGL) and human IgG1. The product was developed by Wyeth Pharmaceuticals, Collegeville, PA, and was acquired by Y's Therapeutics from an undisclosed California biotechnology company in June 2005. Y's said in a press release it received an exclusive, worldwide license from Wyeth for development and commercialization.

The clinical trial is designed to enroll up to 84 patients at 10 leading US transplant centers to evaluate the safety and efficacy of YSPSL for prevention of DGF in kidney transplant recipients. The study will consist of two parts: an open label dose escalation study, and a randomized, double-blind, placebo-controlled study.

Contact: Web site: [www.ysthera.com](http://www.ysthera.com)

### **SynCardia receives approval from Health Canada to market total artificial heart device**

SynCardia Systems, Inc., Tucson, AZ, has received approval from Health Canada to market its implantable heart assist device, CardioWest Temporary Total Artificial Heart (TAH-t) for use in patients eligible for heart transplant who are at risk of imminent death from nonreversible biventricular failure. As a condition of the approval, the company is required to submit annual reports on the marketing experience of the device, including information regarding the total number of units implanted and adverse events.

SynCardia says the Health Canada approval was based on an analysis of preclinical and clinical study data, including an FDA review, showing that 72% of the TAH-t patients survived to 30-days post transplantation, compared to 40% of controls receiving the best available medical care.

The TAH-t received FDA approval in October 2004. Last month, SynCardia was awarded the Frost & Sullivan 2005 Entrepreneurial Company of the Year Award, which recognizes a company that has demonstrated superior entrepreneurial ability in its industry and has a product with "significant market potential."

Contact: Web site: [www.syncardia.com](http://www.syncardia.com)