

LifeCell – Daily News Update

July 13, 2009

Key Industry News:

Publication	tothecenter.com
Headline	<u>Stem Cell Research Taboos Lift Slowly</u>
Gist of the article	<p>Under President Barack Obama, research will now receive more federal funding than before, though ethics is still a barrier for progress.</p> <p>Former President George W. Bush had slowed stem cell research to a crawl by limiting federally supported research to 21 stem cell lines. Now, according to St. Petersburg Times, other privately funded cell lines can become available to the National Institutes of Health through a review process, overseen by a panel.</p> <p>The panel will qualify important stem cell lines, even if they were not discovered in the most ethical situation. So far, the NIH plan to deny lines that have the potential to be used in “therapeutic cloning,” which could create cells specific to certain folks.</p> <p>NIH scientists have the option of deriving stem cell lines from surplus fertility embryos under several conditions, including the donor’s acknowledgement that they will not receive payment or any other kind of medical compensation for their donation.</p> <p>On the other hand, the New York Times explains that researchers in New York are allowed to use state funds to financially compensate women who donate their eggs to embryonic stem cell research. The Empire State Stem Cell Board is assigning committees that will oversee the process of informing and compensating donors.</p>

Publication	economictimes.indiatimes.com
Headline	<u>We have a conservative generic policy</u>
Gist of the article	<p>Johnson & Johnson (J&J) is focusing its attention on Asia and the Indian market. The company recently set up a regional R&D Robert Sheroff, president, GPSG headquarters in China, bringing its global clusters to three. It also inaugurated a late-phase new chemical entity (NCE) facility in Mumbai, its first in the region. Robert Sheroff, president, Global</p>

Pharmaceutical Supply Group (GPSG) spoke to Nina Mehta about the company's plans in the country. GPSG is the production and distribution arm of all J&J's pharmaceutical products. Excerpts:

You have been handling the biotechnology unit. How has the industry grown?

The opportunity of biotech to treat diseases that were not treatable before is still there. So if you look at biologics including stem cells, companies have realised that they want to be in both small molecules and large molecules (biologics). J&J is lucky as we are in both already, and I think most companies are starting to realise that with the acquisition of Wyeth by Pfizer. Two of the new products we are launching this year are biologics. We also have a couple of products in oncology coming out of the biologics space. We are also actively in stem cell therapy.

But you have no plans for biosimilars right now?

I will not say no, nor will I say yes. We are still in the evaluation stage. We do see a role for biosimilars especially in markets such as Asia where affordability is important. Biosimilars can play an important role. We have not made a decision yet but we are evaluating it.

Are you evaluating it more from a regulatory standpoint or a technology one?

I think in the US, the jury is still out on the biosimilar issue due to our concerns of patient safety. We are a big supporter of biosimilars if patient safety is kept at the forefront and that is difficult.

Will the new products be launched only globally or can we expect simultaneous launch in India? Any plans to increase the number of products in India?

They will be global launches. I don't know when they will be launched in India. But I do know that they will be launching in the US and Europe. In fact, Ustekinumab (trade name Stelara), a drug for psoriasis, is already approved in Europe and should be approved in the US soon. Golimumab (trade name Simponi) used for numerous indications related to immunology, will be launched later this year in both the US and Europe. We currently sells 30 drugs in India and hope to increase this in time.

Many big pharma companies are venturing into generics to offset losses that may arise when patent protection for blockbuster drugs expires. What are your plans?

J&J has a pretty conservative generic policy. We do make generic versions of

	our previously patented products. But we have not gone into areas that we never were in. The whole area of small molecules and generics is under evaluation. When it is becoming more and more difficult to get 'me' products, generics could play a role in generating revenue which is needed to do research for 'me' products. The problem is everyone is going there, so it's also becoming highly competitive.
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Publication	theaustralian.news.com.au
Headline	<u>Forlorn Aussies flock to take risky stem cell therapy</u>
Gist of the article	<p>DESPERATE Australians who have paralysis, cancer and neurological diseases, as well as parents of children with intractable conditions such as cerebral palsy, are spending tens of thousands of dollars on unproven and possibly dangerous stem cell treatment at medical clinics in China, India, Mexico and several developing countries.</p> <p>Leading stem cell researchers here and overseas say these clinics threaten the reputation of genuine stem cell treatment, as well as providing false hope to sick people.</p> <p>In Australia, stem cell treatment is used only to treat some blood diseases such as leukemia, and some severe auto-immune diseases such as rheumatoid arthritis.</p> <p>An investigation by The Weekend Australian has found that a burgeoning international stem cell tourism industry is luring vulnerable people into embarking on stem cell therapy that has not been subjected to any of the usual stringent safety protocols, including clinical trials, that apply to potential new medical treatments. The internet is filled with websites offering so-called stem cell treatment for conditions that conventional medicine as yet has no cure for.</p> <p>Although it is impossible to know how many Australians are forking out up to \$35,000 for these treatments, the Australian Stem Cell Centre says it receives at least 500 inquiries every year from people wanting information about stem cell therapy overseas.</p> <p>Kirsten Herbert, clinical adviser to the Australian Stem Cell Centre, said: "It is more prevalent than people think." As a haematologist specialising in cancer, she knows of many patients who have gone overseas for stem cell treatment.</p> <p>"The smattering of anecdotal evidence that these clinics publish on their website carries absolutely no weight, and that is something I try to drum into my patients who are considering going," Dr Herbert said.</p>

	<p>Earlier this year, details of the case of a young Israeli boy who developed tumours after receiving stem cell injections at a clinic in Russia were made public in the journal PLoS Medicine.</p> <p>Three Australian families who have taken their brain-injured children to China for treatment said they had resorted to the unproven stem cell therapy because it was their last hope. They all reported meeting other Australian patients at the overseas clinics.</p> <p>The three children received stem cell injections and intravenous stem cell therapy after contacting Beike, a Chinese biotechnology company that not only provided the stem cells but also oversaw the treatment in hospitals in China. Several requests by The Weekend Australian to speak with Beike went unanswered.</p> <p>Sydney mother Nicole Patterson took her then 15-month-old son Will to China in 2007. She admits it was a leap of faith. "We weren't expecting to bring him home without a brain injury," she said. "We had no illusions that this was a cure."</p> <p>Mrs Patterson believes there has been some improvement in her son's development since the stem cell treatment. She said she was concerned by the lack of scientific rigour demonstrated by Beike, and particularly its unwillingness to offer up its clinical results for scrutiny by the international medical community.</p>
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Publication	arabtimesonline.com
Headline	'Stem cell implants treatment for diabetes not yet confirmed'
Gist of the article	<p>Kuwait Diabetes Society said Saturday that according to international health organizations, no successful or effective treatment for diabetes involving stem cells had been found. The society's Deputy Chairman, Dr. Abdullah bin Nikhi, told KUNA that recent media reports about the discovery of a new treatment for diabetes in Europe through stem cell implants was still at the experimental stage. He noted that the International Society for Pediatric and Adolescent Diabetes had discouraged diabetics from heading to centers claiming to offer such treatment, and reiterated the fact that no indications of the success of such stem cell treatment had surfaced yet. Bin Nikhi called on pediatricians and Kuwait Diabetes Society not to encourage such treatment at present, and asked diabetics to discuss the matter with their doctors before taking any action. Reports over the internet had claimed that a treatment for diabetes, involving stem cell implants, had been discovered and that medical centers were administering the treatment in Europe.</p> <p>Meanwhile, the Ministry of Health has reportedly attached conditions to resume its overseas treatment program which was suspended since last February, reports Al-Watan Arabic daily. The daily added the decision</p>

	limits patients from obtaining medical treatment in foreign countries unless in Saudi-Arabia. The daily also said barren women who apply for treatment must be 40 years or below, and without children. Earlier, decisions permitted women with children who are 43 years and over to go through the process. Furthermore, couple applying for overseas treatment must have visited several obstetrics units in the country for at least two years before they can obtain the ministry's approval, the daily indicated.
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Publication	owensoundsuntimes.com
Headline	<u>Special clinic planned to help stem cell patient waiting for transplant</u>
Gist of the article	<p>A special blood donor and stem cell clinic will be held in Owen Sound this summer to raise awareness and support for Candice Campbell, an 18-year-old West Hill Secondary School student with acute myelogenous leukemia.</p> <p>The clinic will be held on Aug. 5 at the Owen Sound Legion and participants donating blood will be asked to join the OneMatch Stem Cell and Marrow Network. The clinic will offer more than 760 patients currently waiting for a transplant in Canada the chance to find an unrelated stem cell match.</p> <p>As one of those patients, Campbell hopes the clinic in honour of her will help her and others by providing residents with the opportunity to supply a DNA sample through a cheek swab for collection and testing after they donate blood.</p> <p>Hundreds of Canadians need stem cell transplants every year, but 70% of patients are unable find a donor within their own family, which is when they turn to the global stem cell donor database OneMatch.</p> <p>The clinic is being held during the summer as the season is traditionally one of the most difficult times of the year to collect blood. In May, more than 50 fellow West Hill students registered with One- Match to support Campbell.</p> <p>A stem cell transplant requires a patient's diseased marrow/stem cells be replaced with healthy stem cells from a donor. The same stem cells found in bone marrow are also found in circulating blood and either source can be used depending on the individual's needs.</p> <p>Patient champion and West Hill Secondary School teacher, Dian Wood, believes this is the right fit for Owen Sound as it uniquely provides a way for people to understand the need for both blood and stem cell donors as patients continue to fight their illnesses everyday.</p> <p>"I have seen first-hand how this community pulls together while our much-loved student Candice Campbell continues her fight against cancer. Together we can show our support for Candice by giving blood and being tested by OneMatch."</p>

	The clinic will be held Aug. 5 at the Owen Sound Legion from 2 p. m. to 8 p. m. Participants can call 1-888-236-6283 to book an appointment to donate blood or for eligibility information.
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Publication	echo-news.co.uk
Headline	<u>Southend girl, 8, could see with pioneering stem cell treatment</u>
Gist of the article	<p>FAMILY and friends have organised a series of fundraising events to pay for ground-breaking stem cell treatment which could help a blind girl to see.</p> <p>Amy Jarrett, eight, was born with septo-optic dysplasia, a rare genetic brain condition which causes blindness and a series of health problems, including hormone deficiencies and low muscle tone.</p> <p>Her mum, Michelle Russell, 31, of Rochford Road, Southend, is trying to raise £35,000 for her daughter to receive pioneering treatment in China.</p> <p>The treatment involves stem cells being implanted in the spine during sessions over 30 days. It is gruelling for both the patient and their family, particularly when they are so far from home, but results in others have been encouraging.</p> <p>The total raised so far is now £14,000. Last month, friends Dave Cribbs, 39, from Leigh, and Rob Bates, 34, from Southend, travelled more than 800 miles from Land's End to John O'Groats in under 24 hours and raised £4,000. The next event will be a ten-mile walk from Southend to Hadleigh Castle, on July 25.</p> <p>Miss Russell said: "I am still getting more people to join in – the more the merrier. "Everyone is welcome to join in. I am still hoping to get a Chinese dragon for the walk, because we are travelling to China for the operation.</p> <p>"I am really pleased with the amount of money raised. It has been a lot of hard work. I am hoping to have £20,000 by the end of August."People can join the walk by meeting Miss Russell outside the Southend Radio building, to leave for 11am. Alternatively, call Miss Russell on 01702 213871 for details.</p> <p>A school-themed night for over 18s, also in aid of Amy, has been organised for September 25 at St Thomas More School, Westcliff, from 8pm. Two live bands, school dinners and a prize for the best school uniform will also be on offer. Tickets are £15. For more details and tickets, call Karen Patton on 07779519189.</p>