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â€œCell therapy needs more encouragementâ€?

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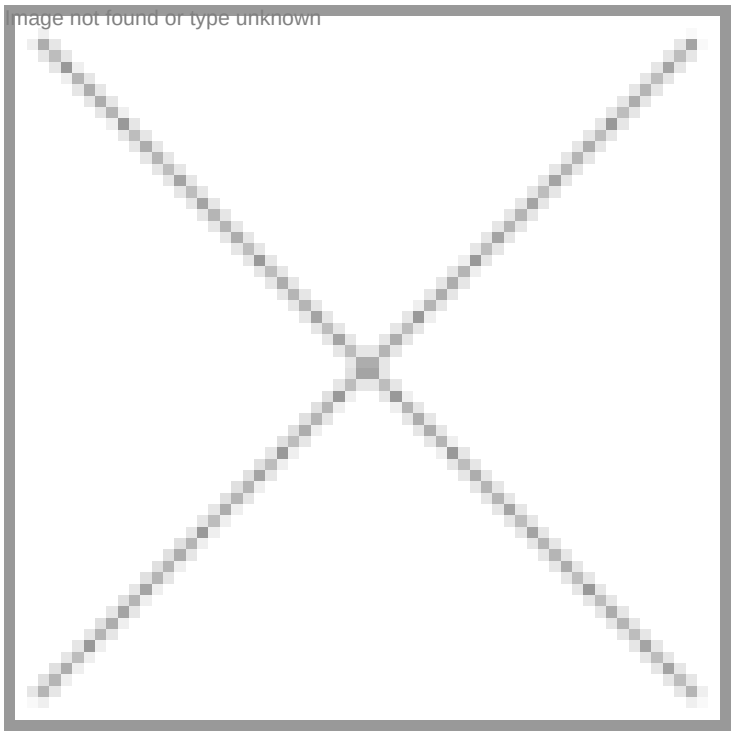

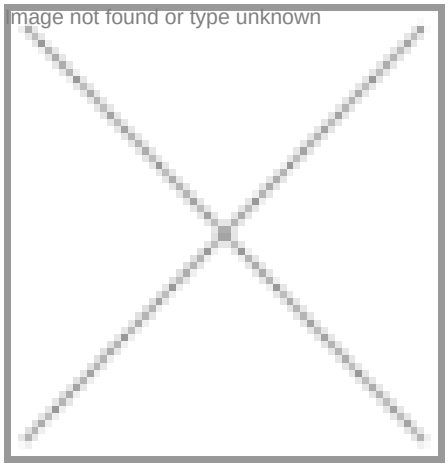

—Satyen Sanghavi, chief scientific officer, RMS Regrow, Mumbai

Cell therapies are emerging as the promising treatment now-a-days as it helps to overcome the limitation of the existing treatment options. Mumbai-based Regenerative Medical Services Regrow (RMS Regrow) in partnership with a South Korean company is exploring the possibilities of cell therapy in India.
In a tete-a-tete with BioSpectrum, Satyen Sanghavi, chief scientific officer, RMS Regrow, talks about his company's working model and partnership with South Korea-based Sewon Cellontech. He also shares his views on the unstructured regulatory

system for stem cells and cell therapy in India

Can you tell us about the genesis of RMS Regrow?
The genesis of the company goes back to the time when I was looking out for a subject for my thesis, while I was pursuing my masters in the UK. Back then, we had a module on stem cell technology and I was interested in the module because it involved tissue engineering and cell culturing. Plus, when I came back to India in 2008, there were small talks about stem cell technology. That is when we came across a South Korea-based company, Sewon Cellontech and we entered into a partnership with them.

Sewon Cellontech develops technology on stem cells and was also licensing out their technology services to various other companies. We got the license from them for Chondron, Ossron and Babycell and as RMS Regrow brought its services here in India. When we were working in partnership with Sewon Cellontech, we realized that it was possible to send the cells to South Korea for culturing and then subsequently they send it back to us in the stipulated time period.

Out of the three services offered by RMS Regrow — which has a good market uptake?
The Babycell technology which focuses on cord blood banking services, brought to India three months back, has picked upin the market. However, for the last one-and-a-half-year, it is Chondron, an autologous biological therapy involving the patient's own cartilage tissue harvest and Ossron cell therapy, an autologous biological therapy involving the patient's bone marrow harvest, which is more interesting even though Babycell has a larger share.

We work on a servicing model. We provide the three services to orthopedics. So, today when a patient walks into a clinicwith a knee pain and is assessed with cartilage damage, the doctor himself may suggest the cell therapy. He will then connect with us to culture the cells. Then there are processes like patient consent forms, hospital consent forms and ethics committee forms. Once we do a biopsy, the cells have to reach the lab within two days. We then send the cells for culturing to Korea and now to our lab in Lonavala and then they send it back to us after culturing.

How did you come up with the idea of setting up a lab in India?
When we started out with RMS Regrow, we worked out on the logistics with our partners. Initially, it was such that there were just four of us. I would handle the logistics and would be in close interaction with the doctors. So, we would know exactly which hospital would start the therapy with which doctor and then accordingly make arrangements for sending the cells for culturing to Korea.

We had to handle operations in a very sophisticated manner because we did not want anything to go wrong. We then started recruiting cell engineers from reputed medical colleges. We then sent them for training to Korea for three months and then sent another batch. That was the time when we started constructing a lab. So in nine months since inception of operations we took up land in Lonavala. By the time we finished the cases in Korea, it gave a chance to each and every surgeon we were in touch with, a case to perform and get hands-on experience on cell therapy.

We started up the lab four months back. So the difference between culturing cells in Korea and that in the lab in India is that --— cells sent for culturing in Korea cost around Rs 3 lakh but at this lab it costs only around Rs 1.5–2 lakh. We have done 8-10 cases in our lab here. So from now on, all the cells will be cultured in this lab.

Before going ahead with cell therapy on a patient, does it need to go through any regulatory approvals?
The requirement was a few results from the initial case studies conducted on patients. Sewon had done their human clinical trials with successful results and since we are partners it applies to us. However, in India, we had to go to the medical regulatory authorities and keep them in the loop before going ahead with any case. Initially, we did inform them several times before a case and also asked written permission for a go ahead. But no regulatory agency in India is ready to give the stamp for a go ahead for cell therapy because they are not aware of the regulations and everyone is scared of giving the go ahead in case something goes wrong in the future. Looking at the uncertainty, today when a doctor is ready to give the treatment when conventional treatments fail, the patient is ready and we are ready to get the cells cultured, we go ahead with the case study. Now we have only an independent ethics committee that comes into the picture.

Human trials for these services have been done in Korea. Any plans to do it in India?
In South Korea, human trials on 800 patients were conducted. However, in India, regulatory authorities have queries that if this works in South Korean patients, will it work on Indian patients too and whether safety results can be shown. So, the first 10-12 cases where we sent cells to be cultured in South Korea was enough to show these authorities that this works on Indian patients as well. In cell therapy, we do not need to show a diverse patient population study. The trials can be conducted in one country and applicable throughout out the world. So, the regulatory authorities here need to have an open

mind.

Any collaboration apart from Sewon Cellontech?
Sewon is a big company and a valuable partner. They have so many projects in the pipeline and have more than 600 people working under them. Plus, they have business in power, agri and biotech. We already have an established partner on their services. We are looking at different other options and are trying to develop cells ourselves, because collaboration brings in additional cost. Now, we have the expertise and technicians who are well trained and have the caliber to develop technologies on their own.

Is the absence of a regulatory framework a hurdle for RMS Regrow?
For stem cells, there is already a draft of guidelines but the government is not ready for a regulatory framework. When we wanted to start RMS Regrow, we went to all the regulatory bodies from the lower order right up to DCGI. But they told us different things and that was because they had less knowledge about the subject. But even now when they do have knowledge about the processes for cell culturing there is no separate guideline for cell therapy. The guidelines applicable for drugs apply for cell therapy too. But there is a huge difference between a drug and a patient cell.

Is there a co-relation between other businesses under the Satyan Group of Companies?
My father started Satyan Pharmaceuticals and has been running it for 25 years along with our insurance company. But there is no co-relation between the three businesses we have right now. Satyan Pharma is into active pharmaceutical ingredient (API) sourcing in South Korea, Singapore and China. We are authorized agents to more than 25 manufacturers here in India. The company has around 22-25 people and the turnover is Rs 500 crore. Then my father felt the need to move to biotechnology because there are not many pharma drugs in the pipeline and big pharma growth is stagnating. There is lot of biotech research happening around the world. So as a strategic decision, RMS Regrow is a way forward for Satyan Pharma.

How does the future look like for RMS Regrow?
We are soon going to start a new therapy service for spinal chord and this will be the use of stem cells where it is easily available. We are expecting a turnover of Rs 10 crore by 2012. In the first year it was Rs 1 crore so it has been quite a growth. We are also looking at developing our own in-house R&D team without any collaboration.

Case Study
It started with an acute pain on the left knee for state level (Madhya Pradesh) cricketer, Ankit Parashar. A 21-year-old middle order batsmen, having a budding career, Parashar's knee pain become unbearable and his performance was affected when he was unable to squat while wicket keeping. He feared that this woulde end his career. He was diagnosed with Osteochondritis Dissecans (OCD), a joint disorder in which cracks form in the articular cartilage and the underlying subchondral bone. In such a condition there is no blood supply to the bone.

Parashar then approached Dr Anant Joshi, an orthopedic surgeon with specialization in arthroscopy, sports medicine and more famously known to be the medical advisory to the BCCI. He then used Regenerative Medical Services Regrow's (RMS Regrow) new technology for cartilage repair therapy Cartilage RMP— Chondron, a procedure where the patient's own cartilage tissue from the healthy articular cartilage is collected, cultured in a lab for 4-6 weeks and then implanted back into the defective area of the cartilage. In Parashar's case, after a biopsy, his cells were cultured for six weeks in a lab in South Korea before it was sent back and implanted in the injured area. "I am hopeful that such a technology is the answer for many athletes who had to end their careers due to repetitive injuries," comments Dr Joshi. Parashar will be back in action by next month and also hopes to make it to the Indian National cricket team.