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Stem cells-The future of therapy

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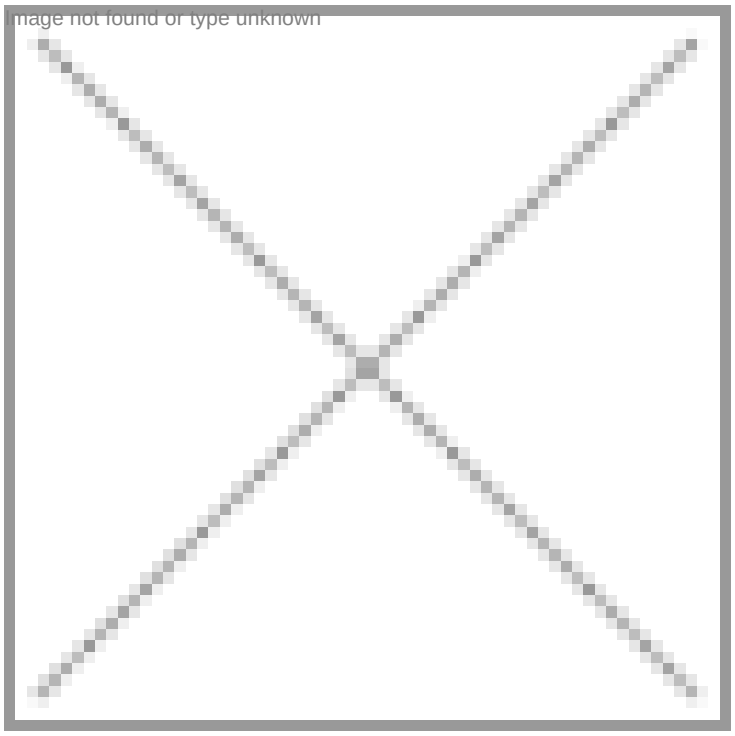

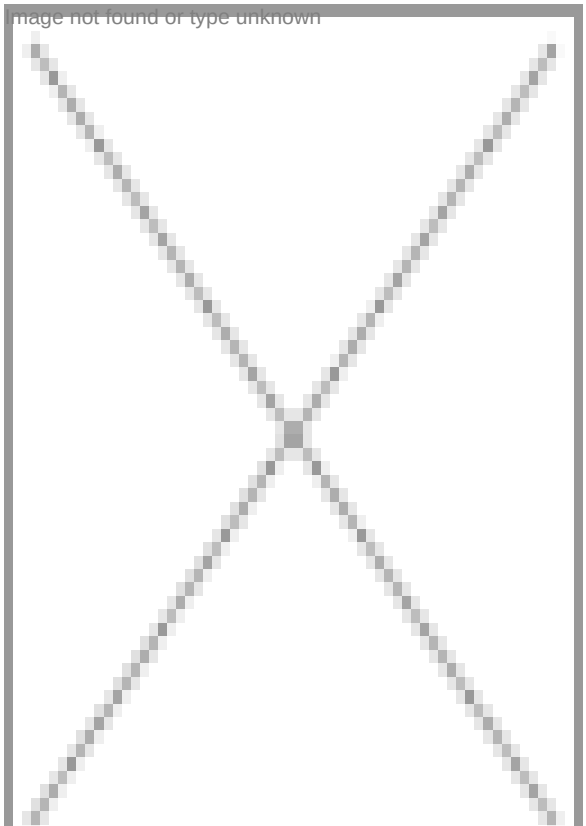

Stem cell market scenario

Indian stem cell companies and research institutes are known for their innovation and R&D expertise. The successes of these companies have encouraged start-ups to enter this promising new sector. Toppers of the prominent stem cell companies share their views on the current trend and future prospects of stem cell research in India.

Bangalore-headquartered Stempeutics Research, a part of the $3 billion (Rs 13,889 crore) diversified Manipal Group, is one of the leading stem cell companies in India. The company is in the process of bringing the first stem cell therapy product in India. While the initial foray of Stempeutics is in bone marrow derived mesenchymal stem cells, Stempeutics is investing heavily on its R&D to bring out some innovative products such as tailor-made cells based on adult stem cells. It is working on alternate sources like Wharton's Jelly, adipose tissue, and dental ligament for mesenchymal stem cells. The company is also investing on leveraging human embryonic stem cells for therapeutics purpose. Stempeutics is also focusing on enhancing the upscaling process of mesenchymal stem cells using latest technology in order to bring down the cost of the end product.

According to BN Manohar, president of Stempeutics Research, "Stem cells would be a major branch of medical treatments and would be a standard cure and practice in the years to come. Regenerative medicine is a rapidly emerging area of biomedical research with enormous therapeutic potential, and this would be an ideal supplement for existing medical treatments.

"The global market for stem cell therapies is expected to be $20 billion (Rs 92,593 crore) by 2010. Adult stem cell therapy currently dominates the global stem cells market with a share of almost 58 percent. There are almost 30 prominent adult stem cell companies in the world. Majority of these companies are based out of the US, followed by the European Union, Israel, Thailand, Canada and Australia," Manohar says. Prominent stem cell companies outside India are Osiris, Organogenisis, Genzyme, Cytori, Aastrom and Theravitae.

Mumbai-based Reliance Life Sciences, which is owned by Mukesh Ambani led Reliance Group, has been a pioneer in stem cell research in India and the company focuses on developing stem cell therapies, right from research, cell processing in cGMP facilities, clinical research and clinical practice. The company is developing a wide range of novel research-led, autologous and allogenic cell therapies and tissue engineered products. Cell-based therapies from Reliance Life Sciences aims to fulfill unmet patient needs in the areas of cardiac disorders, neural degeneration, spinal cord injury, metabolic disorders like diabetes, ophthalmic diseases, hematological diseases, oncological diseases, burns and wound management, diabetic and venous ulcers, and cartilage disorders.

While commenting on the Indian scenario of stem cell therapy, KV Subramaniam, president and CEO, Reliance Life Sciences, says, "India is one of the few countries in the world pursuing stem cell research. But regenerative medicine, comprising stem cell therapies and tissue engineered products, is at a nascent stage in India. According to our estimate, by 2011 about 16.44 crore patients, suffering from diabetes, cardiovascular disorders, neurological disorders, burns and wounds, osteoarthritis, osteoporosis, bone, cartilage (joints & replacements), liver disorders, congenital abnormalities and neoplasms, would benefit from stem cell therapies in India."

"Presently, stem cell therapies have good potential in ocular, cardiovascular, and neurological disorders. There are several companies and institutions engaged in various clinical trials of stem cell research. With growing interest of private companies in this domain and support from government bodies, stem cell therapy holds great potential to emerge as the therapy for several diseases in future," adds KV Subramaniam.

Chennai-based Nichi-In Center for Regenerative Medicine (NCRM) is an Indo-Japan joint venture institute carrying out research, training and clinical applications-protocol development in regenerative medicine, with an emphasis on stem cells, progenitor cells and autologous adult cells with regenerative capability to take them to clinical application, while maintaining the highest ethical and scientific values of international standards. NCRM is the first institute in India to start providing autologous NK cell based immuno-cell therapy (AIET) for cancer and has been providing stem cell isolation, enrichment and expansion services to partner hospitals all over India for various diseases as per Indian Council of Medical Research (ICMR) guidelines.

"Indian stem cell market is quite big. However, we have to educate the public about the possibilities and limitations of the cell-based therapies. With a huge population where lifestyle-related diseases are increasing and with rapidly increasing death rate due to cardiac diseases and cancer, more emphasis is needed for all those diseases that are prevalent in India," says Dr Samuel JK Abraham, director, NCRM.

Bangalore-headquartered Cryo–Save India is a part of Cryo-Save Group, Europe's largest adult stem cell storage bank. The company recently achieved a significant milestone with TUV Rheinland, Germany, conferring the Indian operations an ISO

9001:2008 certification.

“India, as a country, is much more developed and advanced in medical science. It has adapted to the modern medical science than any other Asian countries. With easy accessibility across the nations, India has emerged as the ideal hub for the industry to grow. Considering the growing population in the country, the market is huge and is expected to grow at a rapid pace,” observes VR Chandramouli, managing director, Cryo-Save India.

“Stem cell banking in India is yet to come under a regulatory frame work where government bodies need to spell out theclear-cut procedures for storing the stem cells. As a first step, senior officials at the Ministry of Health and Family Welfare need to lay the process together with the help of an expert committee for stem cell banks and therapy,” adds Chandramouli.

Streamlining guidelines

ICMR and the Department of Biotechnology (DBT) had laid down the fundamental guidelines for stem cell research and therapy in 2007, but in the absence of laws specific to the issue, the guidelines were set aside. Apparently in India we are in a stage to formulate the norms governing stem cell banking and the storage procedures, opines Chandramouli.

The guidelines put forth jointly by ICMR and DBT have not become a law so far. Government needs to create a separatetask force on stem cells research and therapy and see how India can leverage its intellectual talent and become a global leader in this field. In countries like Malaysia excellent support is provided by the Malaysian Biotechnology Corporation. It provides seed funding, R&D funding and export funding for start-up companies (BioNexus Status Companies).

Also it provides 10-year tax benefits from the year the company starts making profit, duty exemptions and a host of benefits for promoting stem cell companies. Indian government should provide these benefits to stem cell companies based on certain evaluation. Also on stem cell clinical trials front, government needs to think on fast track approval process considering it as ‘orphan’ drug status – like what FDA is doing in the US, suggests Manohar of Stempeutics.

Future forward

India needs to speed up its activities related to human clinical trials (as per cGCP standards). There are only few dedicated companies focusing on real research and clinical trials. The current stem cell therapy market in India is approximately $540 million and it is expected to grow rapidly. The country is also becoming an attractive destination for global stem cell companies and research institutes in the areas of clinical trials/clinical research, stem cell research and contract manufacturing.

Recent approval of clinical trials of stem cell-based drugs by the Drug Controller General of India (DCGI) has created immense interest among global stem cell players to conduct their clinical trials in India. Well-defined guidelines, efficient and speedy processes for approving clinical trials by regulatory bodies and availability of vast patient pool makes India a good destination for conducting clinical trials.

ICMR supported by DCGI has drafted guidelines to conduct clinical trials in India in an ethical and scientific manner. ICMR has formed an expert stem cell committee to validate and recommend trials in India. DCGI recently made registry of all clinical trials mandatory with Clinical Trials Registry- India (CTRI) registry – so that all trials can be monitored for proper conduct as per international norms.

Availability of skilled manpower and initiatives taken by the government in creating good infrastructure for stem cell research are attracting foreign institutes and private companies for collaborative research with Indian institutes and private companies. The initiative taken by the DBT in creating a world-class stem cell research center in Bangalore is another positive step in nurturing value-added stem cell research in India.

Another area where India can take a lead in stem cells is the stem cells production technology i.e. large scale upscaling of stem cells. It is an area where private players can take a lead in the global market in the next three to four years. Global stem cell players may outsource their ‘production’ process to India if India can show the cost/quality advantage.

India has the opportunity to be a global force in biotechnology and stem cell research can be an important constituent of this aspect of global leadership in this frontier technology area.

— Pradeep Kumar in Bangalore