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Stem cell trial with watchdog nod

SUBHRO SAHA

Timely intervention saved Amal Bhattacharya's life following a massive heart attack last winter. But the 51-year-old telecom executive, the sole bread-earner in the family, was forced into premature superannuation since he can't exert himself after losing a large chunk of heart muscle.

For the first time in India, there is concrete hope for patients like him, with a Bangalore-based biotechnology company gearing up to bring what it says will be the first scientifically-proven stem cell therapy product into the Indian market in 2012.

The product, to be launched in intravenous and intra-muscular injection form, will be initially targeted at acute myocardial infarction (AMI or heart attack) and critical limb ischemia (CLI or blocked blood vessels in limbs) patients.

Stempeutics Research, developing stem cell-based medicinal products, with facilities in Bangalore, Manipal and Kuala Lumpur, has obtained the Drug Controller General of India (DCGI)/Indian Council of Medical Research (ICMR) approval for conducting multi-centric Phase I/II combined clinical trials for its two most advanced programmes. The ongoing projects are indicated in these two life-threatening/debilitating conditions.

"This is the first allogeneic stem cell clinical trial approved in India. A Phase III study is planned in 2011 and

we have to wait for the outcome and data consolidation for about six months, after which we are planning to hit the market. Before that, our concern is to assess the safety and efficacy of the investigational new drug in the clinical trial," B.N. Manohar, president, Stempeutics Research, told Metro from Bangalore.

Recent advances in research have confirmed stem cell efficacy in treating heart

cathlab services, Medica Superspecialty Hospital.

Naik, however, feels before the stem-cell medicine can become equally effective in treating heart-attack patients with damaged cardiac muscle, the problem of cardiac arrhythmia, often resulting from heterogenous cell growth following stem cell injection, needs to be addressed properly.

"We are taking all these potential pitfalls into account while fine-tuning our product at this point," said Radhika Bobba, the medical director of Stempeutics Research and in-charge of the clinical trials.

"Our focus is on bone marrow-derived mesenchymal stem cells to be used as a drug for therapeutic treatment of various degenerative diseases. Besides AMI and CLI, several other programmes are currently awaiting regulatory approval in conditions like chronic obstructive pulmonary disease, dilated cardiomyopathy, liver cirrhosis, osteoarthritis and diabetes mellitus," she added.

In Calcutta, CordLife Sciences India, the partly owned Indian subsidiary of Singapore-based cord blood banking major CordLife, announced last December that it would soon bring its expertise of using cord blood stem cells to treat cerebral palsy to the city.

Chennai-based LifeCell, India's first private cord blood bank, is also doing advanced R&D in the therapeutic domain with stem cells.

THERAPY HOPE

- Heart attack
- Strokes
- Spinal cord injury

FUTURE USE

- Regenerative medicine
- Individual vaccines
- Cost-effective cell therapy

attacks, strokes and spinal cord injuries. The three key areas of future application of stem cells, which are used to replace or initiate the production of other cells that are damaged or missing, are regenerative medicine, individual vaccines and cost-effective cell therapy.

Doctors in the city are bullish on the impact of a stem cell-derived medicine being available off the shelves soon. "Such a therapeutic product could be very useful in treating critical limb ischemia in particular, where sometimes the disease is so extensive, diffuse and multi-sited that corrective intervention is not feasible," said J. Naik, director, cardiology and