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Stempeutics to launch its stem cell based new drug in India by 2012

Saturday, February 27, 2010 08:00 IST
Suja Nair-Shirodkar, Mumbai

Stempeutics Research, a biotechnology company developing stem cell based medicinal products, is all set to introduce its investigational new drug (IND) in India by 2012. The drug is being developed in India is for acute myocardial infarction and critical limb ischemia. Stempeutics had obtained the approval from DCGI and ICMR last year to start clinical trials using allogenic mesenchymal stem cells from the bone marrow. It is the first DCGI and ICMR approved clinical trial using adult allogenic mesenchymal stem cells from the bone marrow.

The company has contracted Acunova, a Bangalore based CRO, to conduct the clinical trials in India and Malaysia. The trials for acute myocardial infarction are being undertaken in Bhagawan Mahaveer Jain Heart Centre, Bangalore; Care Hospital, Hyderabad; S A L Hospital and Medical Institute, Ahmedabad; and M S Ramaiah Memorial Hospital, Bangalore.

The Critical Limb Ischemia Study is being conducted in Amrita Institute of Medical Sciences, Kochi; Sir Ganga Ram Hospital, New Delhi; M S Ramaiah Memorial Hospital, Bangalore and in Bhagawan Mahaveer Jain Heart Centre, Bangalore. Both the studies are multi centre, double blind, randomised and placebo controlled.

BN Manohar, president, Stempeutics said, "The recruitments for the trial have been completed and the process of analysis is going on at the moment. It will be announced once we are get the interim results since it yet has to be analysed."

The company said that their investments in the last three years in R&D has clearly helped them to move into the clinical trial phase last year. Speaking about the investment Manohar informed, "We have invested nearly 100 crore in R&D across our centres in India and Malaysia. Though we conduct research on both adult stem cells as well as embryonic stem cells, we believe that adult stem cells, especially the stem cells from the bone marrow, are closer to



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'ISM has found foothold in several countries'



Dr T Thirunarayanan, secretary of CTMR

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the market and thus have invested heavily in this area." Further he said that the company has also collaborated with many government agencies and universities in conducting collaborative research in the area of stem cells.

The company has currently filed 14 patent applications in India, six PCT applications and corresponding patent applications in US and Asian countries. The company also has many new products in pipeline which are stem cell based drugs. Some of them are for chronic obstructive pulmonary disease, dilated cardiomyopathy, liver cirrhosis, diabetes mellitus and osteoarthritis.

Speaking about Malaysia he said that Malaysian operation is key to their growth plan in the South East Asia region. When asked to give the details of the trials in Malaysia he said, "The details of the trials being undertaken in Malaysia will be announced shortly once the entire approval process is completed."

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