



Stempeutics gets Malaysian Regulatory approval for conducting Clinical Trials in Malaysia

First Indian company to get Malaysian Regulatory approval for stem cell product

Bangalore April 14th 2011 – Stempeutics Research a group company of Manipal Education & Medical Group announced today that Malaysian Regulatory Authority has granted clearance of the company's Investigational New Drug (IND) for conducting clinical trials in patients with Osteo Arthritis (OA) and Cerebral Stroke (CS) indications. OA involves degeneration of joints, caused by breakdown of articular cartilage. It is characterised by pain and swelling of joints. CS is the sudden death of brain cells in a localized area due to inadequate blood flow. Without blood to supply oxygen and nutrients brain cells quickly begin to die. In this clinical trial IND will be tested for safety & efficacy of these two indications.

Being the first of its kind clinical trial in Malaysia, it took almost 10 months to get Malaysian Regulatory clearance. Stempeutics proposal was reviewed by Malaysian Regulatory authorities and the committee accepted the study as Phase I/II clinical trials. Malaysian Regulator's clearance of IND is one of Stempeutics's significant accomplishments towards its goal of bringing a safe, effective and affordable stem cell based drug in Malaysia in the near future.

Stempeutics Malaysia was incorporated in 2007 and has established a state-of-the-art research facility in 2008 at Technology Park Malaysia. It established strong Research relationship with Institute of Medical Research (IMR) and University of Malaya (UM) in 2009. The company was awarded the BioNexus status in 2007. Stempeutics has done some pioneering work in the isolation, up-scaling and large scale production of adult Mesenchymal Stem Cells for therapeutic applications. In 2008, it established a Production facility which has been inspected and confirmed to

- *Stempeutics received Malaysian Regulatory's clearance for its IND for conducting Phase I/II clinical trial*
- *IND is based on mesenchymal stem cells derived from donated Bone Marrow*
- *Clinical trials are multicentric, placebo controlled, double blind, addressing two diseases i.e. Osteo Arthritis (OA) and Cerebral Stroke (CS)*
- *Stempeutics has established large scale production of Mesenchymal Stem Cells at TPM and the facility has been approved by Malaysian Regulatory for GMP compliance*
- *Based on the successful outcome of clinical studies Stempeutics plans to introduce the FIRST stem cell based drug - available off the shelf in Malaysia in 2014*



be compliant for GMP standards for production of its IND for clinical trials. To-date Stempeutics has filed 6 patents in Malaysia and published 8 peer reviewed international papers.

Speaking at the Press Conference at Malaysia, Mr. BN Manohar, CEO, Stempeutics Research said “We are the only stem cell company in Malaysia to have achieved this significant milestone. The IND has been developed based on international standards under stringent quality processes. We have also planned for a large scale upscaling of mesenchymal stem cells facility in Malaysia and we expect that it will be the most cost effective product globally”.

“It is necessary to ethically and scientifically explore the full potential of stem cell to transform biomedical therapy. Stem cell would significantly enhance medical treatment in Malaysia” said Dato’ Iskandar Mizal Mahmood, CEO of Malaysian Biotechnology Corp (BiotechCorp) at the press conference. “Regenerative medicine is a rapidly emerging area of biomedical research with enormous therapeutic potential worldwide, and this would be an ideal supplement for existing medical treatments. The Global market for stem cell therapy is expected to be US16 billion in 2014 and in Malaysia the market for stem cell therapy is approximately US157 million”, Dato’ Iskandar added.

Meanwhile Mr. Madhu Kumar, Country Manager, Stempeutics Research Malaysia commented, “Stem cell therapy aims at addressing the root cause of the disease rather than the symptoms. Our goal is to bring out a stem cell based drug in the near future using mesenchymal stem cells. 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 in the near future based on adult stem cells. There will be continuous research for each disease so as to improve product development for effective therapy. Research will be conducted on effective cell number, route of transplantation etc. We want to become an undisputed leader in the stem cell area in this part of the world”.

Based on the successful outcome of the clinical trial, Stempeutics plans to introduce its first stem cell based drug which is aimed to be available in Malaysia in the near future

For media inquiries, kindly contact:

Jisha, Stempeutics Research at Jisha.brigit@stempeutics.com

About Stempeutics Research

Stempeutics Research is a leading stem cell research company developing stem cell based medicinal products, with GMP compliant facilities in Bangalore and Manipal (India) as well as in Kuala Lumpur (Malaysia). The Company is funded by Manipal Education & Medical Group and Cipla and it was incorporated in January 2006.



Stempeutics has been doing extensive research and developmental studies to understand the biology and differentiation pattern of adult mesenchymal stem cells (MSCs) in order to make successful use of these cells for meeting unmet medical needs. Currently the Company is focusing on 8 products covering Cardiovascular - Acute Myocardial Infarction (AMI), Critical Limb Ischemia (CLI) & Dilated Cardiomyopathy (DCM), Orthopedics – Osteoarthritis (OA), Respiratory - Chronic Obstructive Pulmonary Disease (COPD), Endocrinology - Diabetes Type II (DM), Central Nervous System - Cerebral Stroke (CS) and Gastroenterology - Liver Cirrhosis (LC) diseases for which there are no effective treatments available. These 8 products are under various stages of development. Stempeutics product name is “Stempeucel” and it is based on allogeneic MSCs derived from bone marrow of healthy voluntary donors.

Stempeutics has completed pre clinical studies demonstrating the appropriate safety profile of Stempeucel product. Stempeutics has also completed initial Phase I/II human clinical trial approved by Indian FDA i.e. Drug Controller General of India (DCGI) for AMI & CLI indication. The Company has filed for Phase IIB/III approval for CLI. In addition, Stempeutics has recently received Phase II clinical trial approval from Indian FDA for COPD, LC, OA and DM indications. In Malaysia, Stempeutics has got Malaysian FDA i.e. National Pharmaceutical Control Bureau (MALAYSIAN REGULATORY) approval for CS and OA clinical trials. Stempeutics’ long-term objective is to market its products in the Asian, European and North American markets.

While the initial foray of Stempeutics is in bone marrow derived MSCs, Stempeutics is investing on its R&D programs to bring out some innovative products in the near future based on MSCs derived from Wharton’s Jelly, Adipose Tissues and Dental Pulp. The Company is investing money on large scale up scaling of products so as to make the product affordable for the larger population of the society. It is also working on a point-of-care medical device project for providing autologous therapy using ADSC.

Stempeutics obtained “Bio Nexus” status in Malaysia – granted by the Malaysian Biotechnology Corporation and its facility is approved by MALAYSIAN REGULATORY for GMP compliance. In India the facilities are approved by Department of Scientific & Industrial Research (DSIR) and ISO 9001:2008 certified. It is also inspected by Indian Council of Medical Research (ICMR) and confirmed to meet their standard guide lines. Scientists working at Stempeutics have filed 19 patents and they have published 28 peer reviewed international publications.

For more information visit www.stempeutics.com