



Press Release  
For Immediate Publication

## **Stempeutics product *stempeucel* gets DCGI clearance to start Phase II clinical trial for four debilitating diseases**

**Osteo Arthritis, Diabetes Mellitus – Type2, Liver Cirrhosis and Chronic Obstructive Pulmonary Disease**

**Bangalore January 20<sup>th</sup>, 2011** – Stempeutics Research a group company of Manipal Education & Medical Group announced today that Drug Controller General of India (DCGI) has granted clearance of the company's Investigational Medicinal Product "Stempeucel" for conducting Phase II clinical trials in patients with Osteo Arthritis, Diabetes Mellitus – Type2, Liver Cirrhosis and Chronic Obstructive Pulmonary Disease. Stempeucel product is developed from allogeneic mesenchymal stem cells derived from donated bone marrow using Stempeutics proprietary technology. Earlier the company has received approval from DCGI for Phase I/II clinical trial for Acute Myocardial Infarction and Critical Limb Ischemia in March 2009. Stempeutics is funded by Manipal Group and Cipla.

DCGI referred Stempeutics proposal to Indian Council for Medical Research for their review and recommendations. Being the first of its kind stem cell product developed in India, ICMR constituted an expert stem cell committee to examine the proposal and the committee accepted the study as Phase II clinical trials. The DCGI's clearance of Stempeucel product for the four debilitating diseases is one of Stempeutics's significant accomplishments towards its goal of bringing safe, effective and affordable stem cell based product in India in the near future. India becomes one of the leading countries after USA to enter this phase of Stem Cell research.

Commenting on the DCGI's approval, Mr **BN Manohar**, CEO, Stempeutics Research said "We would like to thank the regulatory bodies - DCGI & ICMR for encouraging the stem cell companies in harnessing the potential of stem cells in the drug development program. We are the only stem cell company in India to have achieved this significant mile stones. Our team is working towards launching the first "off-the-shelf" adult stem cell product in the Indian market by the end of 2013. Stempeucel product has been developed based on international standards under

- ***Stempeutics received DCGI clearance for the company's Investigational Medicinal Product – "Stempeucel" for Phase II clinical trials for four debilitating diseases***
- ***It is a multicentric, placebo controlled, double blind, allogeneic clinical trials addressing Osteo Arthritis, Liver Cirrhosis, Diabetes Mellitus-Type2 and Chronic Obstructive Pulmonary Disease***
- ***Stempeutics established large scale production of Mesenchymal Stem Cells for Clinical Trials using its patented upscaling process***
- ***Based on the successful outcome of clinical studies Stempeutics plans to introduce the FIRST stem cell based drug - available off the shelf in India by end of 2013.***

stringent quality processes. In India we have pioneered large scale upscaling of mesenchymal stem cells and we expect that it will be the most cost effective product globally”.

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### **Osteoarthritis**

Osteoarthritis (OA) involves degeneration of joints, caused by breakdown of articular cartilage. It is characterised by pain and swelling of joints. Current treatment is largely limited to pain killers, and at later stages – joint replacement. Mesenchymal stem cells may differentiate into cartilage and bone and hence cure the degenerated joints in osteoarthritis. Current study is designed to evaluate the safety and efficacy of “Stempeucel” when injected into the knee joint and to find out the best dose of stem cell for osteoarthritis.

### **Chronic Obstructive Pulmonary Disease**

Chronic obstructive pulmonary disease (COPD) is a disease of the lungs in which the airways become narrowed. This leads to a restriction to the flow of air to and from the lungs causing shortness of breath. Currently the available treatment options are targeted at only symptomatic relief of COPD, which do not provide long term benefits to the patients. Mesenchymal stem cells are thought to stimulate the endogenous stem cells and help them to differentiate into alveolar epithelium, thus repairing the lung damage and improving pulmonary function. This study involves the evaluation of safety and efficacy of “Stempeucel” in COPD and finding the appropriate safe and effective dose for the disease.

### **Alcoholic Liver Cirrhosis**

Liver Cirrhosis is a condition where normal liver is replaced by fibrosis, scar tissue and regenerative nodules leading to loss of liver function. Currently, there is no cure for liver cirrhosis except liver transplantation. The option of transplantation is limited by availability of liver and risk of rejection. The objective of the present study is to evaluate if “Stempeucel” injected near the liver are safe and lead to improvement in the patient’s condition. This is done by various blood tests and confirmed by liver biopsy and imaging techniques. The study will also evaluate different doses of “Stempeucel” to find out the most safe and effective dose.

### **Diabetes Mellitus – Type2**

Diabetes mellitus Type2 is a disease in which a person has high blood sugar, either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced. Current therapies for diabetes include oral hypoglycaemic drugs and insulin injections in addition to dietary management. They do not address the root cause i.e. lack of functional cells in pancreas and peripheral insulin resistance. This study is planned to see if stem cells injected into patients with diabetes, can trigger pancreatic resident stem cells / progenitors to form new cells. If successful, stem cell therapy possibly may result in permanent cure for

diabetes. The objective of this study is to evaluate the safety and efficacy of a single intravenous dose of “Stempeucel” in type 2 diabetes mellitus and to find out the most suitable dose of stem cells.

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### **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 is in the final stage of getting Malaysian FDA i.e. National Pharmaceutical Control Bureau (NPCB) 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 NPCB 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](http://www.stempeutics.com)

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