

Stempeutics launches FIRST Human Stem Cell Clinical Trial in Malaysia for Cerebral Stroke using GMP certified facility at Kuala Lumpur

Malaysia becomes one of the leading countries after USA to have reached this level

Kuala Lumpur, May 3rd, 2010 – Stempeutics Research Malaysia Sdn Bhd., a group company of Manipal Education & Medical Group announced today that Medical Research and Ethics Committee, MoH, Malaysia has granted clearance for conducting human clinical trials in patients with Ischemic Cerebral Stroke (CS) using investigational new drug (IND) based on Mesenchymal Stem Cells derived from donated bone marrow. Ischemic CS is the sudden death of brain cells in a localized area due to inadequate blood flow. When blood supply to a part of the brain is affected, oxygen and nutrients fails to reach the affected area and brain cells quickly begin to die. Ischemic CS is an important cause of mortality and morbidity all over the world. It is a major cause of death in the ASEAN countries as well. This clinical trial will be conducted as per GCP norms for studying the safety and efficacy of IND administered via intravenous route.

Being the first of its kind clinical trial of stem cell based product in Malaysia, it took almost 6 months to get the MREC clearance. MREC constituted an expert committee to examine the proposal and the committee accepted the study as a Phase I/II clinical trial. The trial will follow internationally accepted principles governing ethical conduct of clinical research and the protection of human subjects i.e. regulatory oversight, continuous supervision from independent Data Safety Monitoring Board, fair subject selection, informed consent, trial sites with appropriate facilities and staff for the conduct of study, competent and qualified investigators, patient monitoring and timely reporting of all serious adverse events. MREC's clearance of clinical trial is one of Stempeutics significant accomplishments towards its goal of bringing safe, effective and affordable stem cell based product in Malaysia in the near future.

Stempeutics also received National Pharmaceutical Control Bureau (NPCB) certification for its manufacturing facility located at Technology Park Malaysia for conforming to the requirement of current Good Manufacturing Practices (cGMP) in accordance with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guides and its relevant annexes for Isolation, Processing and Storage of Mesenchymal Stem Cells. Stempeutics is the FIRST stem cell company in Malaysia to have obtained this conformance certification.

- *Stempeutics received MREC clearance for Phase I/II human clinical trial for its IND based on Mesenchymal Stem Cells derived from donated Bone Marrow*
- *It is a multicentric, placebo controlled, double blind, allogenic clinical trial for patients with Ischemic Cerebral Stroke.*
- *78 patients will be recruited under this trial*
- *Stempeutics has established world class stem cell lab for large scale production of Mesenchymal Stem Cells using innovative upscaling process*
- *Stempeutics received NPCB certification for cGMP compliance in accordance with PIC/S GMP guide lines for its manufacturing facility in Malaysia*
- *Based on the successful outcome of clinical studies Stempeutics will be seeking MREC approval for large scale Phase III clinical trial*

The study is a multicentric, randomized, double blind, placebo controlled, allogenic clinical trial. The study envisages recruiting 78 patients in the early phase after an Ischemic stroke. Half of them, chosen randomly, will be given 2 million MSCs/ kg body weight by intravenous infusion within 10 days of an acute ischemic stroke. A similar number of patients will receive a placebo. The patients will be followed up at regular

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intervals up to 12 months. The principal outcomes statistically tested will be safety and efficacy as determined by global outcomes as measured by the NIH Stroke Scale (NIHSS). There will be several secondary efficacy endpoints including a MRI scan. Safety study will be done by close follow-up of patients clinically, radiologically and by measuring biochemical parameters to diagnose any adverse events. An independent data safety management board will closely monitor the parameters to ensure patient safety.

Speaking at Press conference, **The Minister of Science, Technology and Innovation of Malaysia Datuk Seri. Dr. Maximus Johniti Ongkili** said, “The Global market for Stem Cell therapies is expected to be \$ 20 billion by 2010. Adult Stem Cell therapy currently dominates the Global Stem Cells Market with a share of almost 58%. Independent studies have identified Malaysia as a market with exciting potential in stem cell research and therapy – estimated at US\$157 million with year on year growth of 12%. Thus the establishment of Stempeutics is a significant step with multiple benefits – enhancing foreign direct investment of up to RM30 million to Malaysia, a wealth of resource in international research and expertise and expanding access and exposure for Malaysian talent in stem cell research”. He further added “In the area of human capital development, Stempeutics intends not only to shape and nurture fresh talent but also to widen the scope and raise the bar for Malaysian post graduate talent to focus on breakthrough stem cell research. This will set the foundation in developing Malaysia as a stem cell research and therapy hub”.

Speaking at the Press conference, **The CEO of Biotechcorp, Dato’ Iskandar Mizal Mahmood** said “Stem cell companies should ethically and scientifically explore the full potential of stem cells to transform medicine and offer new hope to millions of people. We believe that Stem Cells would be a major branch of Medical treatment and would be a standard of cure and practice in the years to come. Regenerative medicine is a rapidly emerging area of biomedical research with enormous therapeutic potential world wide, and this would be an ideal supplement for existing medical treatments”.

Mr. Madhukumar, Country Manager, Stempeutics Research Malaysia said, “Stem Cell therapy aims at addressing the root cause of the disease rather than the symptoms. Our goal is to bring out stem cell based drug in the near future using Mesenchymal Stem Cells. We will hit the market with our first product by end of 2012. 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 innovative products in the near future based on adult stem cells from other sources as well. There will be continuous research for each disease so as to improve product development for effective therapy. We want to become an undisputed leader in the Stem Cell area in this part of the world”.