



## Stempeutics announces clinical trial outcome of India's FIRST stem cell product **stempeucel**<sup>™</sup><sub>CLI</sub>

### Establishes strategic alliance with Cipla for product marketing

Bangalore April 27<sup>th</sup> 2010 – Stempeutics Research Pvt. Ltd., a group company of Manipal Education & Medical Group announced today that it has completed the initial Phase I/II clinical trial of its product “Stempeucel-CLI”. This multi centric, placebo controlled, double blind trial was approved by DCGI last year (2009). Stempeucel-CLI is a stem cell based product developed using mesenchymal stem cells derived from donated bone marrow, for Critical Limb Ischemia (CLI) patients. Critical Limb Ischemia term is used for patients with chronic non-healing wound/ ulcers or gangrene and ischemic rest pain. To market its product Stempeutics has established strategic alliance with India's leading pharmaceutical company Cipla.

The clinical trial product has been manufactured using Indian FDA guidelines under ISO 9001:2008 & cGMP compliant lab and the clinical trial has been conducted as per the cGCP norms. The outcome of the trial shows (a) No rejection of allogenic MSCs (b) the product is safe & well tolerated and no adverse events attributed to the product and (c) Positive efficacy trend i.e. Improvement in ABPI (ankle brachial pressure index) & ankle pressure, decrease in number of ulcers and no significant increase in number of amputations. The initial trial outcome establishes safety and it requires further study to establish the efficacy.

To market Stempeutics products, Stempeutics has established strategic alliance with India's leading pharmaceutical company, Cipla. Under this alliance, Cipla is sponsoring upto Rs. 50 crores in Stempeutics in the initial phase for research and development of stem cell based products. Further investment may be considered at a later date. Cipla will extend technical support for production and handle “go-to-market” activities of the product. As part of this deal Cipla gets the marketing rights of the product being developed by Stempeutics.

- Stempeutics completes DCGI approved initial Phase I/II clinical trial of “Stempeucel-CLI” off the shelf stem cell based product
- Trial data establishes safety of the product and positive trend in efficacy
- Will be seeking DCGI approval for large scale clinical trial
- Enters into strategic alliance with India's leading pharmaceutical company Cipla
- As part of this alliance Cipla is sponsoring Research & Development of stem cell based products in Stempeutics
- Cipla is sponsoring upto Rs 50 Crores in the initial phase based on Stempeutics requirements. Further funding may be considered by Cipla at a later date
- In return Cipla gets marketing rights of the products being developed by Stempeutics



Speaking about the Cipla-Stempeutics tie-up, Mr Amar Lulla, Joint Managing Director Cipla said “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. We are very happy to tie-up with Stempeutics because of their R&D strength in developing world class stem cell products starting from basic research, pre clinical studies, large scale upscaling and conducting multi centric clinical studies as per international standards.”

Speaking about the product development & Cipla tie-up Dr Ranjan Pai, CEO, Manipal Education & Medical Group said, “We are progressing well towards our goal of bringing the first stem cell based product to the Indian market in the near future. Stempeutics has done pioneering work in the isolation, up-scaling and large scale production of adult Mesenchymal Stem Cells for therapeutic applications. By far, it is the first stem cell company in this part of the world to come upto this level. On the Cipla tie-up he said that the synergistic combinations of Cipla & Stempeutics are based on the strong values of their founders and powered by their corporate vision, and is poised to bring out novel stem cell based products for mankind and transform India into a global player in stem cell therapeutics”.

Speaking at the Press conference Dr Jaideep Gogtay, Medical Director, Cipla said “Adult Stem Cell therapy currently dominates the Global Stem Cells Market with a share of almost 58%. The expected current stem cell therapy market in India is approx US\$ 540 million and expected to grow rapidly. While the opportunity is good it is essential that cost of stem cell treatment becomes less so that it is affordable by a common man. It is therefore important to develop innovative production techniques for upscaling and make the product affordable”.

Speaking at the Press conference Mr B.N.Manohar, President, Stempeutics Research said, “Stempeutics obtained DCGI approval last year for conducting multi centric phase I/II allogenic clinical trials for its two most advanced programs, indicated in acute myocardial infarction (AMI) and critical limb ischemia (CLI). CLI trial has shown positive results and AMI trial result is expected in August 2010. He said that six more indications i.e. chronic obstructive pulmonary disease, dilated cardiomyopathy, liver cirrhosis, osteoarthritis and diabetes mellitus are currently awaiting regulatory approval. He further added that Stempeutics’ long-term objective is to market its products in the European & North American markets”.

#### CLI Clinical Trial

Incidence of CLI is estimated to be approximately 1000 patients per million per year and 10 to 40% of them are at the risk of primary amputation. The goal of CLI clinical trial is to assess the safety and efficacy of the investigational new drug (IND) administered intramuscularly in patients with critical limb ischemia.

The safety of the IND is measured by the number of adverse events attributed to the treatment arm as compared to the placebo group. The efficacy of the IND is measured by assessing relief of rest pain – rest pain scale (+4 to 0), healing of necroses and ulcerations in the target limb and prevention of amputation of target limb. In addition the study includes assessment of increase in transcutaneous partial oxygen pressure (TcPO<sub>2</sub>), Ankle brachial pressure index (ABPI) and neoangiogenesis (new vessel formation) in the target limb assessed by magnetic resonance angiogram (MRA).

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