

Gets bionexus status in Malaysia

12 April 2011 | News



Mr B N Manohar,
CEO, Stempeutics

Stempeutics, a stem cell company developing stem cell-based medicinal products, with facilities in Bangalore, Manipal and Kuala Lumpur, is in the process of bringing the first stem cell therapy product to the Indian, European and North American markets



Bangalore-based Stempeutics Research, a group company of Manipal Education and Medical Group, opened the first-of-its-kind stem cell research facility in Malaysia, citing the ease in getting early approvals. Since its inception in 2008, Stempeutics has been working together with the leading medical institutions in Malaysia, to drive long-term research activities to further strengthen its leadership position in the area of stem cell research.

Malaysian Presence

As a result of collaborative efforts, Stempeutics Research announced in May 2010, that it has received clearance from Medical Research and Ethics Committee, Ministry of Health, Malaysia, 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.

Stempeutics became the first international company in Malaysia to get the bionexus status from BiotechCorp. Also it has received National Pharmaceutical Control Bureau (NPCB) certification for its manufacturing facility for conforming to the requirement of current good manufacturing practices (cGMP), in accordance with the Pharmaceutical Inspection Co-

operation Scheme (PIC/S) GMP guidelines 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 has spent nearly 30 crore to set up a facility at Malaysia, with a strength of 20 members. "We are planning to invest another 20 crore in Malaysia to develop our first product from there. The phase II clinical trials for our product 'Stempeucel' have been successful. We aim to complete the phase III trial by 2013 and launch the product in the market by 2014," says Mr B N Manohar, CEO, Stempeutics.

"We have a very favorable environment in Malaysia where we get tax benefits up to 10 years from the date we start making profit. Along with that we have other customs duty incentives. With NPCB approval, we can go to nearly 20 other countries which come under the Organization of Islamic Conference (OIC), without any further clinical trials," adds Mr B N Manohar while commenting on the presence in Malaysia.

Global Challenges

On the challenges while entering the global market, Mr Manohar says, "In the case of other countries, the main challenge is the regulatory procedures. Especially, since we are focusing on the stem cell market with no specific verified guidelines, we need to ensure that it is universally acceptable. With the source being of Indian origin, its acceptability abroad again poses as a challenge for us while we plan to venture abroad. The regulatory guidelines in clinical trials has to be followed. Money too plays a major factor when you plan to enter the global market."