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CONDITIONAL LICENCE

Stempeutics eyes late-stage trial waiver for stem-cell drug

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BENGALURU

Stempeutics Research Pvt. Ltd, a company part-owned by **Cipla Ltd**, on Monday said it hopes to get a conditional licence to sell its stem-cell drug in India, which would help it raise money to complete the drug's late-stage trials.

On Monday, drug authorities in the European Union (EU) granted the so-called orphan drug status for the company's product Stempeucel. The status entails a smoother road to regulatory and marketing approvals for drugs being developed to treat rare diseases.

Stempeucel, made from stem cells from bone marrow, is used to treat a rare condition of reduced blood flow to limbs from Buerger's Disease. Roughly 2 million Indians suffer from this disease. "Now that we have completed phase two trials on 120 patients, and safety and efficacy has already been established, we want the Drug Controller General of India (DCGI) to give us conditional marketing approval, so that we could sell the drug to limited patients and not go for phase three trials," said B.N. Manohar, managing director and chief executive of the Bengaluru-based firm.

The company wants to sell the drug to 100-200 patients before completing clinical trials, which will cut research costs and help patients who have no other cure. Further trials would take another three years and cost around ₹10 lakh per patient.

If launched in India, Stempeucel may cost more than ₹1 lakh per vial. Manohar said the firm is working with **Lonza Group Ltd** of Switzerland to cut the price through large-scale production.

"We would monitor patients to whom the drug has been sold and give back the data to the DCGI, in a way combining the phase three and four of trials," he said. However, even if it does not get such a conditional marketing licence, the company will go ahead with phase three trials since Stempeucel is its "most promising drug", Manohar said.

Manohar called receiving the orphan designation in the EU an important regulatory milestone. "The benefits include 10 years of market exclusivity from product launch in the EU, fee reductions, as well as access to the central authorization procedure," he said.

The European drug regulator had earlier given an orphan drug status to Iloprost, developed by **Schering AG**, which treats a similar condition. Stempeutics believes it now has a stronger case to get such an approval in India.

"We are open to giving an orphan drug status and conditional licence if a highly regulated market has done so earlier in a rare disease. Depending on the drug and the molecule, our subject experts would assess the suitability and need for Indian population," said Dr G.N. Singh, DCGI.

Founded in 2006 with help from the Manipal Group, where Manohar worked earlier, the company received a ₹50 crore investment from Cipla in 2009.

Stempeucel has patent rights in the US, China, Australia, New Zealand, Singapore and South Africa.

"So far, there have not been any stem-cell drug exports from the country. The area is niche and extremely innovative," said P.V. Appaji, director general of Pharma Exports Promotion Council.

According to S. Srinivasan, an associate with All India Drug Action Network, an independent network of NGOs working for improving access to essential medicines, there have been phase three trial waivers for some drugs. "In this case, nothing should stop the company from seeking an extension of phase two or to market it for free," Srinivasan said.