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FDA approval for Strides' injections

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Onco Therapies, a wholly owned subsidiary of Strides Arcolab, has received US FDA approval for Cladribine Injection of 1 mg/ml packaged in 10 mg/10 ml single-dose vials.

Cladribine is part of the oncology portfolio licensed to Pfizer in January 2010 for the US market. The product is expected to be launched shortly and belongs to the group of cancer-fighting medications known as antineoplastics, and specifically to the group of antineoplastics known as antimetabolites. Strides Arcolab has also received US FDA approval for Clindamycin Injection, USP, an antibiotic used to treat bacterial infections. Clindamycin injection will be available in three single-dose vial sizes and in pharmacy bulk packaging.

RMS-Regrow gets GMP certification

Regenerative Medical Services, a leading biotechnology company in India focused on the delivery of the most advanced stem cell therapy treatment, received certifications for good manufacturing practices (GMP), good laboratory practices (GLP) and good clinical practices (GCP) from the British Standard Institution, an international accreditation body.

The GMP, GLP and GCP certifications received by RMS-Regrow validate the procedures adopted and followed at RMS-Regrow. These certifications place RMS Regrow in the select league of companies that have been awarded such a global honor. â€œThis is a landmark achievement for us as this certification has come within the first two years of the company's operations since September 2009 after receiving its ISO 13485:2003. This significant milestone enables the company to advance the global commercialization of cellular therapies, live up to the commitment of exceeding customer expectations and maintaining manufacturing excellence,â€? said Dr Satyen Sanghavi, chief scientific officer at RMS.

CryoSave gets WHO-GMP certificate

Cryo-Save India, a subsidiary of the leading Europe-based family stem cell banking company Cryo Save Group NV, has become the first to receive the World Health Organisation's Good Manufacturing Practices (WHO-GMP) certification. Cryo-Save India is headquartered in Bangalore with a state-of-the art fully automated adult stem-cell storage facility.

The WHO-GMP certification guarantees superior quality, safety and effectiveness in production. In the case of bloodproducts like stem cells, the WHO-GMP guidelines govern every aspect of production and testing which includes construction, design and maintenance of the premises, qualification of equipment, extraction process, laboratory condition, component preparation and validation and cross contamination, mix-ups and labelling, that can impact the quality of the product.