BioSpectrum the business of Bio & Health Sciences

Cipla's HIV drug for children gets FDA nod

04 June 2015 | News | By BioSpectrum Bureau

Cipla's HIV drug for children gets FDA nod

Cipla has announced that it has received the United States Food and Drug Administration (US FDA) approval for its innovative formulation, Lopinavir/ ritonavir (LPV/r) 40mg/ 10 mg oral pellets, for paediatric specific treatment for infants.

The pellets are to be sprinkled on sweetened porridge for infants and administered to them. The pellets are produced by melt-extrusion technology and are enclosed in capsules.

Cipla has been working for many years in collaboration with Ms Diana Gibb, Professor of Epidemiology, Senior Programme Leader and Honorary Consultant Paediatrician at Medical Research Council Clinical Trials Unit at UCL (University College London) towards development of this novel child-friendly formulation which has been approved by the US FDA under the President's Emergency Plan for AIDS Relief (PEPFAR) program.

"We are extremely proud to have developed this innovative formulation of LPV/r oral pellets for infants and young children. Cipla has been committed to the cause of HIV/AIDS for over two decades. This innovative way of drug delivery through oral pellets for some of society's youngest AIDS sufferers reiterates our commitment to provide access to life saving medicines in the fight against HIV/ AIDS," said Mr Subhanu Saxena, MD and Global CEO, Cipla.

Dr Jaideep Gogtay, chief medical officer, Cipla said, "Lopinavir/ Ritonavir is a preferred antiretroviral in paediatric patents and this unique drug delivery system is a breakthrough in paediatric specific treatment for infants. The traditionally available antiretroviral liquid formulations and tablets have their own challenges when it comes to treating infants. LPV/r oral pellets 40 mg/ 10 mg should be used in combination with other antiretroviral agents for the treatment of HIV-I infection in paediatric patients weighing 5 kg and above and who can have semi-solid food."