Press Release

Cipla Announces US FDA Approval for the World's First Paediatric Lopinavir and ritonavir Oral Pellets for the Treatment of AIDS in Infants and Young Children

India, Mumbai, 3rd June 2015: Cipla Limited, a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients, today announced that it has received US FDA approval for an innovative formulation — Lopinavir/ ritonavir (LPV/r) 40mg/ 10 mg oral pellets — for paediatric specific treatment for infants.

Cipla has long recognized the lack of access to life saving child-friendly formulations for the treatment of HIV, which prompted it to develop an innovative formulation of LPV/r oral pellets. 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 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 US FDA under the President's Emergency Plan for AIDS Relief (PEPFAR) program.

Commenting on the development, **Mr. Subhanu Saxena, MD & Global CEO, Cipla Ltd.** said: "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."

Dr Jaideep Gogtay, Chief Medical Officer, Cipla Ltd. 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."

Dr Peter Mugyenyi, Executive Director of the Joint Clinical Research Centre (JCRC) in Uganda and a leading International authority on treatment of HIV/AIDS in Africa said: "I am delighted to hear of Cipla's breakthrough in getting US FDA approval for the world's first paediatric Lopinavir and ritonavir oral pellets for the treatment of AIDS in infants and young children. The reason I welcomed Dr Y K Hamied's invitation to sit on the Cipla Board as an Independent Board Director is because Cipla's motto of "None shall be denied", and the company's dedication to work for patients who are most in need. This product is a first step in

making accessible more modern and appropriately formulated treatment available to the most vulnerable of HIV patients – young children."

Globally 3,200,000 children were living with HIV in 2013 and 240,000 children were newly infected with HIV (UNAIDS — The Gap Report 2014). Although antiretroviral therapy can be life saving for these children, only 24% are currently on treatment. One third of the children born with HIV without treatment die before their first birthday and 50% die before they turn two.

About Cipla Limited

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. For more than 70 years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 150 countries. Our portfolio includes over 1500 products across wide range of therapeutic categories with one quality standard globally.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognised globally for the pioneering role played in HIV/AIDS treatment as the first pharmaceutical company to provide a triple combination anti-retroviral (ARV) in Africa at less than one dollar a day and thereby treating many millions of patients since 2001.

Cipla's research and development focuses on developing innovative products and drug delivery systems and has given India and the world many 'firsts' for instance Triomune. In a tightly regulated environment, the company's manufacturing facilities have approvals from all the main regulators including USFDA, UKMHRA, WHO, MCC, ANVISA, and PMDA which means the company provides one universal standard both domestically and internationally.

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