Generic HIV treatment submitted for FDA approval

Aurobindo Pharma, in conjunction with ViiV Healthcare and the Clinton Health Access Initiative, Inc. (CHAI) have announced that Aurobindo Pharma has submitted an Abbreviated New Drug Application (ANDA) for dolutegravir 50mg, for Tentative Approval, to the Food and Drug Administration (FDA), for the treatment of HIV. This is the first ANDA for a generic version of dolutegravir, less than two years after FDA approval of Tivicay® (dolutegravir) for sale in the United States.

Upon receiving Tentative Approval from the FDA, Aurobindo Pharma will be able to supply dolutegravir 50mg via the President's Emergency Plan for AIDS Relief (PEPFAR) programme, following completion of required local regulatory approval process, in the licensed countries outside of the United States, as per the agreement signed between Aurobindo Pharma and ViiV Healthcare in 2014.

This submission comes less than five years after ViiV Healthcare and CHAI signed an agreement to collaborate with the goal of bringing innovative formulations of medicines for the treatment and prevention of HIV/AIDS to people living with HIV in developing countries, on an affordable yet sustainable basis.

CHAI and ViiV Healthcare worked together to identify a generic partner after conducting feasibility research. Following this initial joint work, ViiV Healthcare submitted necessary documentation to the FDA providing a selective waiver letter for the five-year period of New Chemical Entity (NCE) exclusivity that would have otherwise prevented FDA review and Tentative Approval of Aurobindo Pharma's ANDA at this time.

Dr. Dominique Limit, CEO, of ViiV Healthcare, said, "This first ANDA for a generic dolutegravir confirms that our strong commitment to thinking and acting differently to pursue new ways to expand access to our medicines, for people living with HIV in countries where the need is most pressing, is working."

David Ripin, PhD, Executive Vice President, and Chief Scientific Officer, CHAI, said: "UNAIDS has set global public health goals calling for 90 percent of those who are HIV-positive to know their status, 90 percent of those identified to be linked to treatment programs, and 90 percent of those in treatment to achieve undetectable viral load. To tackle these complex challenges, targeted efforts to facilitate access to HIV treatment medicines, such as dolutegravir, are needed."

N. Govindarajan, Managing Director at Aurobindo Pharma, said, "We are pleased to be part of this innovative partnership designed to accelerate access to medicines for treating HIV. Aurobindo Pharma is committed to HIV care and aims to achieve the goals of wider access to HIV treatment, care, and support; seeking to address the spread of HIV through development of this newer class of drugs and fixed-dose combinations for low- and middle-income countries. "

The filing by Aurobindo Pharma is the second result of the agreement between CHAI and ViiV Healthcare. It comes less than six months after another generic manufacturer announced that it had received Tentative Approval from the FDA for paediatric formulations of another ViiV Healthcare antiretroviral (also under PEPFAR for sale in licensed countries outside of the United States), through innovative collaboration with ViiV Healthcare and CHAI.