BioSpectrum the business of Bio & Health Sciences ASIA EDITION

FDA approves Gilead's Stribild

28 August 2012 | Regulatory | By BioSpectrum Bureau

FDA approves Gilead's Stribild

Singapore: The US Food and Drug Administration (FDA) has approved Stribild, a complete once-daily single tablet regimen by Gilead Sciences for HIV-1 infection for treatment-naÃ¯ve adults. Stribild, referred to as Quad prior to FDA approval, combines four compounds in one daily tablet: elvitegravir, an integrase inhibitor; cobicistat, a pharmacoenhancing agent; emtricitabine and tenofovir disoproxil fumarate.

Applications for marketing approval of Stribild are now pending in Australia, Canada and the European Union. In the developing world, Gilead has granted multiple Indian manufacturing partners and the Medicines Patent Pool the right to develop generic versions of Stribild and distribute them to 100 developing countries. These agreements include a complete technology transfer of the manufacturing process for the single tablet regimen.

"Over the past decade, co-formulated HIV medicines have simplified therapy for many patients and have become standard of care," said Dr Paul Sax, clinical director of the Division of Infectious Diseases at Brigham and Women's Hospital, Boston, Professor of Medicine at Harvard Medical School, and principal investigator of one of the Stribild pivotal studies. "Today's approval of Stribild will provide physicians and their patients an effective new single tablet treatment option for individuals starting HIV therapy for the first time."

The approval of Stribild is supported by 48-week data from two pivotal phase III studies in which the single tablet regimen met its primary objective of non-inferiority compared to Atripla and to a regimen containing ritonavir-boosted atazanavir plus Truvada. Today's approval is also supported by Chemistry, Manufacturing and Controls (CMC) information on the individual components of Stribild and the co-formulated single tablet regimen.

"For much of the company's 25-year history, Gilead has focused on the development of improved treatments and simplified regimens for HIV," said John C. Martin, PhD, Chairman and Chief Executive Officer, Gilead Sciences. "Therapies that address the individual needs of patients are critical to enhancing adherence and increasing the potential for treatment success, and we are proud to introduce a new single tablet regimen for the healthcare and patient communities."

Stribild is the third single tablet HIV regimen developed by Gilead. The first, Atripla, was approved in 2006 and is marketed by Gilead and Bristol-Myers Squibb in the US. The second single tablet regimen, Complera, which combines Gilead's Truvada and Janssen R&D Ireland's rilpivirine, was approved in 2011.