BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

US FDA approves GSK's asthma drug

29 August 2014 | Regulatory | By BioSpectrum Bureau

Singapore: GlaxoSmithKline (GSK) has announced that the United States Food and Drug Administration (US FDA) has approved Arnuity Ellipta (fluticasone furoate inhalation powder), a once-daily inhaled corticosteroid (ICS) medicine for maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older. However, Arnuity is not indicated for relief of acute bronchospasm.

It has been approved in the dosages of 100 mcg and 200 mcg. It is administered once daily via the dry powder inhaler Ellipta, which is also used across a range of other approved respiratory medicines in the GSK portfolio.

"The approval of Arnuity Ellipta is an important development for GSK and our expanding respiratory portfolio. It is the first asthma treatment from our new portfolio to have gained approval in the US and enables us to begin expanding the range of medicines that we offer to physicians and appropriate patients," Mr Darrell Baker, SVP and head, GSK global respiratory franchise, said.

The efficacy and safety of this drug have been evaluated in more than 3,600 patients with asthma.