BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# Novartis Cushing's drug gets first-ever FDA nod

17 December 2012 | Regulatory | By BioSpectrum Bureau


**Singapore:** Novartis received US FDA approval for Signifor (pasireotide) injection for the treatment of adult patients with Cushing's disease, for whom pituitary surgery is not an option or has not been curative.

Signifor is the first medicine to be approved in the US that addresses the underlying mechanism of Cushing's disease, a serious, debilitating endocrine disorder caused by the presence of a non-cancerous pituitary tumor which ultimately leads to excess cortisol in the body. This approval follows a unanimous recommendation from the FDA Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) in support of the use of Signifor.

"The FDA approval of Signifor for Cushing's disease brings a novel pituitary-directed therapy to patients with limited treatment options," said Mr Herve Hoppenot , president, Novartis Oncology. "This milestone reinforces Novartis' commitment to addressing unmet needs and advancing treatments for rare pituitary-related disorders."

The approval is based on data from PASPORT-Cushings (Pasireotide clinical trial portfolio-Cushing's disease), the largest randomized phase III study to evaluate a medical therapy in patients with Cushing's disease. Results from the study found that a decrease in mean urinary-free cortisol (UFC), the key measure of biochemical control of the disease, was sustained during the treatment period in most patients, with a subset of patients reaching normal levels. The study also showed that certain clinical manifestations of Cushing's disease tended to improve.

In April 2012, the European Commission approved Signifor for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed. Other worldwide regulatory filings for pasireotide for this use are also underway.