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FDA nod for Novartis Cushing's disease drug Signifor

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Novartis's Signifor approved for Cushing's disease

Singapore: The US FDA's Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) has voted unanimously in support of the use of Signifor (pasireotide) for the treatment of patients with Cushing's disease who require medical therapeutic intervention.

"We are encouraged by favorable advisory committee recommendation for pasireotide in Cushing's disease and will work closely with the FDA as it completes its review of our application," said Dr HervÃ?Æ?Ã?Â© Hoppenot, president, Novartis Oncology. "There is a significant unmet medical need for Cushing's disease patients and Novartis is committed to providing the endocrinology community with a novel therapeutic approach for this rare and debilitating endocrine disorder."

The recommendation was based on data from clinical trials of pasireotide, including 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. Although not obliged to follow the recommendation, the FDA can seek the advice of its advisory committees as it reviews and decides whether to approve treatments.

Results from the PASPORT-CUSHINGS study found that mean urinary-free cortisol (UFC), the key measure of biochemical control of the disease, was rapidly decreased and sustained in a majority of patients, with a subset of patients reaching normalized levels. The study also showed that, on average, as UFC levels were reduced, clinical manifestations of Cushing's disease improved.

The most frequently reported adverse events (AEs) (>10%) by investigators for pasireotide were diarrhea, nausea, hyperglycemia, cholelithiasis, abdominal pain, diabetes mellitus, injection site reactions, fatigue and increased glycosylated hemoglobin (HbA1c), with most events being Grade 1-2. The safety profile of pasireotide was similar to that of other somatostatin analogs (SSA) with the exception of the greater degree of hyperglycemia.

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