Novartis Drug SOM230 is First Medical Therapy to Show Efficacy in a Phase III Trial in Cushing's Disease, a Debilitating Hormonal Disorder

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EAST HANOVER, N.J., Sept. 22 /PRNewswire-FirstCall/ -- Novartis Pharmaceuticals Corporation ("Novartis") (NYSE: NVS [1]) announced today that the results of a Phase III study of SOM230 (pasireotide) showed a reduction in cortisol levels in patients with Cushing's disease, a condition in which a benign (non-cancerous) pituitary tumor causes the adrenal glands to produce excess cortisol and can be fatal(1). Results will be presented at the 14th Congress of the European Neuroendocrine Association (ENEA).

At six months, the majority of evaluable patients (91/103) experienced a reduction from baseline in urinary free cortisol (UFC) levels, the main measure of biochemical control of the disease. UFC levels were normalized in 26% of patients randomized to SOM230 900ug twice daily, meeting the primary endpoint of the study. Additionally, median UFC was reduced by 48% in both the 900ug and 600ug dose groups. After 12 months of treatment, results confirmed the durability of the effect(1).

On average, as UFC levels were reduced, clinical symptoms of Cushing's disease improved including reduction of blood pressure, total cholesterol, weight and body mass index (BMI)(1).

Cushing's disease is caused by a benign tumor in the pituitary gland that secretes adrenocorticotropic hormone (ACTH), which triggers the adrenal glands to produce excess cortisol. Cortisol is a powerful steroid hormone that regulates a broad range of physiologic functions, including metabolism and immunity(2). Cushing's disease can cause severe cardiovascular and metabolic-related illnesses or death(3),(4). There are currently no approved medicines to treat Cushing's disease(1).

"There is a critical need for a medical treatment for people with Cushing's disease because currently available options, such as surgery or radiotherapy, are ultimately not effective for many of the patients who suffer from this d
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