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Novartis' Signifor receives FDA approval

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Novartis has announced that the US Food and Drug Administration (US FDA) has approved Signifor long-acting release(LAR)(pasireotide), a next-generation somatostatin analog (SSA) for injectable suspension and intramuscular use. It is used for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. Signifor LAR has been studied and found effective in both medically naÃ¯ve patients with acromegaly who have had prior surgery or for whom surgery was not an option, as well as patients whose disease is not fully controlled on first generation SSAs.

Acromegaly is a rare, debilitating endocrine disorder caused by the excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1).

This FDA approval was based on two multicenter Phase III studies, C2305 and C2402, which respectively examined medically naÃ¯ve patients who have had prior surgery or for whom surgery was not an option and patients with acromegaly inadequately controlled on first generation SSAs. In both studies, higher rates of full biochemical control (defined as mean GH level < 2.5mcg/L and normal IGF-1 levels) were achieved with Signifor LAR compared to a first generation SSA.

"The FDA approval of Signifor LAR for acromegaly marks an important day for physicians and patients living with difficult-to-treat pituitary conditions and underscores our continued commitment to helping patients manage rare diseases. We are pleased that a new treatment option is now available to help address the serious impact of uncontrolled acromegaly, and are

optimistic about providing this much needed treatment to other patients worldwide in the near future," said Mr Bruno Strigini, president, Novartis Oncology.