

Japanese regulators grant additional approval for the sale of Ipsen's rare cancer drug in Japan

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Bringing in much needed relief for millions of gastroenteropancreatic neuroendocrine cancer patients, the Japanese regulators have approved the sale of the drug Somatuline by Teijin pharma in Japan. The drug was developed by French drug firm Ipsen and is approved in Japan for the treatment of acromegaly and pituitary gigantism since 2012.

The request for the additional approval was filed in July 2016, based on Ipsen's investigational, pivotal phase III randomised placebo-controlled trial (CLARINET) in 204 patients with GEP NET conducted in 14 countries, and an open-label single group multicenter Phase II trial (J-001) in 32 patients with NET that Teijin Pharma conducted in Japan. This approval establishes Somatuline as the first drug available in Japan for the treatment of pancreatic NET.

NETs, malignant tumors arising from neuroendocrine cells, are relatively rare, with about 1.3 pancreatic NET patients per 100,000 people in Japan. The primary treatment is surgical removal.

Mr Harout Semerjian, Executive Vice-President & President, Specialty Care International & Global Franchises, Ipsen said, "We are pleased that Somatuline® is now also available for Japanese patients suffering from gastrointestinal and pancreatic neuroendocrine tumors. In line with our commitment to serve NET patients worldwide, this is a significant step after our partner Teijin launched Somatuline® for the treatment of acromegaly and pituitary gigantism in Japan in January 2013."

"It is our great pleasure to now have the capacity to provide a new therapeutic option to NET patients in Japan, said, Mr Akihisa Nabeshima, President of Teijin Pharma said We will continue to focus on drug discovery and improve the quality of life of patients by offering them new treatment options to fulfill unmet medical needs."

Teijin pharma had also recently inked a deal with Merck for the development, manufacturing and commercialization of the investigational preclinical antibody agent targeting the protein Tau, according to its press release. Tau and its level

fluctuations are associated with Alzheimer's disease and other diseases affecting the nervous system.

"Securing alliances with leading industry partners is a key part of The Teijin Group strategy, Teijin Pharma believes that Merck's strong neuroscience expertise makes it well suited to maximize the potential of this candidate," Mr Nabeshima, said in the release.