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An Ongoing, Double-Blind, Randomized, Placebo-Controlled Clinical Trial Investigating the Efficacy and Safety of Somatuline® Depot (Lanreotide) Injection in the Treatment of Carcinoid Syndrome

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Background: Carcinoid syndrome occurs when a carcinoid tumor secretes hormones such as serotonin that reach the systemic circulation; it is usually the result of liver metastases and is characterized by multiple symptoms, most often flushing and diarrhea. The presence of somatostatin receptors on 80%-90% of these tumors makes them an ideal target for treatment with somatostatin analogues (SSAs). SSAs are the mainstay of treatment for carcinoid syndrome. Lanreotide is an SSA approved in >50 countries for the treatment of neuroendocrine (carcinoid) tumors, but currently approved in the US only for the treatment of acromegaly. Somatuline® Depot (SD) is the prolonged-release formulation of lanreotide, available as a ready-to-use, pre-filled syringe for deep subcutaneous administration every four weeks. The current study evaluates the safety and efficacy of lanreotide versus placebo for the control of symptoms associated with carcinoid syndrome.

Design: An ongoing, multicenter, Phase 3/4 study consisting of a 16-week double-blind, randomized, placebo-controlled phase evaluating SD in patients with carcinoid syndrome followed by a 32-week initial open-label (IOL) phase during which all patients receive SD. In countries where SD is not approved for carcinoid syndrome, patients who continue to benefit from the drug at the end of the IOL phase will have the option to participate in a long-term open-label phase (LTOL) and continue receiving SD. The key inclusion criteria are: age ≥18 years at first dosing; histopathologically confirmed carcinoid tumor, or a carcinoid tumor of unknown location with liver metastases (documented by biopsy), a history of carcinoid syndrome (diarrhea and/or flushing) in patients naïve to SSTas or responsive to conventional doses of octreotide (≤30 mg of long-acting every four weeks or ≤ 600 µg/day of subcutaneous short-acting). The primary endpoint is the usage (percentage of days) of subcutaneous octreotide required to control the symptoms (diarrhea and/or flushing) associated with carcinoid syndrome during the double-blind phase. Target enrollment for this study is 100 adult patients. There are currently 80 patients enrolled in the study, and patient recruitment is ongoing in 12 countries. The highest recruiting countries to date are the USA (37 patients) and Ukraine (18 patients).