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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 – Update on the Current Status

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Background: Carcinoid syndrome occurs when a carcinoid tumor secretes hormones such as serotonin that reach the systemic circulation, usually as the result of liver metastases and 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). Lanreotide is an SSA approved in >50 countries for the treatment of neuroendocrine (carcinoid) tumors and currently approved in the US 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.

Objective: Update on the current study which is designed to evaluate the safety and efficacy of lanreotide versus placebo for the control of symptoms associated with carcinoid syndrome.

Design: A multi-center, Phase 3 study consisting of a 16-week double-blind, randomized, placebo-controlled phase of SD in patients with carcinoid syndrome followed by a 32-week initial open-label phase (and the option of a long-term open-label extension phase), during which all patients receive 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 SSAs 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. The study will enroll an estimated 100 adult patients in approximately 65 sites worldwide.

Status: Patient recruitment is ongoing in 12 countries. There are currently 34 patients included in the study.