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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 certain amines and peptides that bypass the liver and are secreted into the bloodstream. It is usually the result of metastases to the liver and is characterized by several symptoms; the most common being flushing and diarrhea. Somatostatin receptors are found on 80%-90% of these tumors, and somatostatin analogues (SSAs) are widely used to treat carcinoid syndrome. Lanreotide (Somatuline® Depot) is an SSA approved in >50 countries for the treatment of acromegaly and symptoms associated with carcinoid syndrome; for now it is approved in the US for the treatment of acromegaly only. Lanreotide has a prolonged-release formulation that is presented as a ready-to-use, pre-filled syringe administered via deep subcutaneous injection every four weeks. This study evaluates the safety and efficacy of lanreotide versus placebo for the control of symptoms associated with carcinoid syndrome.

Methods: This is an ongoing, 48-week Phase 3/4 study consisting of a 16-week double-blind, randomized, multicenter, placebo-controlled phase evaluating 120 mg lanreotide in patients with carcinoid syndrome followed by a 32-week open-label phase during which all patients receive 120 mg lanreotide. The key study 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), and a history of carcinoid syndrome (diarrhea and/or flushing); and either SSA treatment-naïve or responsive to conventional doses of long-acting octreotide (≤30 mg every four weeks) or responsive to daily doses of ≤ 600 µg of subcutaneous short-acting octreotide. 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 objective is to randomize 100 patients.