

SPINET: a Randomized, Double-blind, Placebo-controlled Phase III Study of Lanreotide Autogel/Depot (LAN) in Patients with Advanced Lung Neuroendocrine Tumors

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Background: The large phase III CLARINET study demonstrated antitumor efficacy LAN 120 mg vs placebo (PBO) for metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) of grade 1 or 2 (Ki-67 <10%). Surgery remains the mainstay for localized lung NETs; other approved treatment options for advanced lung NETs are limited. The aim of the SPINET study is to evaluate the safety and antitumor efficacy of LAN 120 mg in patients with advanced lung NETs.

Methods: SPINET is a large multinational, multicenter, randomized, double-blind, PBO-controlled phase III study (NCT02683941; EudraCT: 2015-004992-62). Main inclusion criteria: adult patients with well-differentiated typical or atypical, metastatic and/or unresectable lung NETs, positive somatostatin-receptor imaging, ≤1 course of chemotherapy, ECOG PS 0–1. A total of 216 patients will be enrolled from 80 sites across the USA, Canada, and Europe. Patients will be randomized 2:1 to receive either LAN (120 mg every 28 days) or PBO both alongside best supportive care, until progressive disease (PD)/death or unacceptable toxicity. Patients receiving placebo who experienced PD may opt to receive LAN 120 mg in an open-label extension phase. All patients who experience PD will be followed to document survival, quality of life (QoL), and subsequent anticancer treatments.

Results: The primary endpoint is progression-free survival (PFS, time from randomization to progressive disease [PD]/death), and will be assessed based on central review using RECIST v1.1. Main secondary endpoints include PFS according to local review, objective response rates, overall survival, changes in plasma chromogranin levels, LAN pharmacokinetics, QoL, and safety.

Conclusion: The ongoing SPINET trial is the first prospective, placebo-controlled, randomized study designed to assess the effect of LAN 120 mg on typical and atypical carcinoid lung NETs.