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Design of a Phase 2, Prospective, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy and Safety of Lanreotide Depot 120 mg in Patients With Well Differentiated, Advanced Lung, or Thymus Neuroendocrine Tumors (NETs)

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Background: The randomized, double-blind, placebo-Controlled Study of Lanreotide Antiproliferative Response in Neuroendocrine Tumors (CLARINET) showed that treatment with the somatostatin analog (SSA) lanreotide depot was associated with significantly prolonged progression-free survival (PFS) vs placebo in gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Lanreotide depot injection subsequently became the first FDA-approved somatostatin analog (SSA) for this indication. Like GEP-NETs, lung and thymic NETs express somatostatin receptors. We designed a randomized phase II study to assess whether lanreotide depot may prolong progression-free survival (PFS) in these NET tumor subtypes.

Methods: This multi-institutional study will enroll an anticipated 126 patients with advanced lung or thymic NETs. The study will include patients with grade 1 or 2 tumors who have positive somatostatin scintigraphy and are somatostatin-

analog naïve**.** Tumor progression within the last 12 months will be assessed for eligible patients. Patients will be randomized 2:1 to receive lanreotide depot 120 mg via deep subcutaneous injection plus best standard of care (BSC) or placebo (BSC). With a 2:1 randomization, an estimated 100 PFS events (disease progression or death) on both arms will provide an 80% power to detect a statistically significant treatment effect using a two-sided log rank test at a significance level of $\alpha=0.05$.

Results: Anticipated results include data on the primary endpoint of PFS in both arms, as well as data on secondary endpoints which include objective radiologic response rate, overall survival, effects on plasma chromogranin A, and safety/tolerability.

Conclusions: Therapeutic agents for the treatment of patients with advanced lung or thymus NETs treatment are currently limited. This study will provide data on the efficacy of lanreotide depot for patients with these understudied malignancies.