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CLARINET FORTE Baseline Characteristics: Lanreotide Autogel 120 Mg (LAN) Every 14 Days in Patients with Progressive Pancreatic or Midgut Neuroendocrine Tumors During a Standard First-Line LAN Regimen

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BACKGROUND: Lanreotide autogel (LAN) is a long-acting somatostatin analog used to treat somatostatin receptor-positive (SSTR+), gastroenteropancreatic neuroendocrine tumors (GEP-NETs). In CLARINET, LAN 120 mg every 28 days (q28d) significantly improved progression-free survival (PFS) versus placebo in metastatic, SSTR+ GEP-NETs. CLARINET FORTE (NCT02651987) is an ongoing phase 2 study assessing the safety and efficacy (centrally assessed median PFS) of a reduced LAN 120 mg dosing interval (q14d) in progressive pancreatic NETs (panNETs) and midgut NETs.

METHODS: Eligible patients had well-differentiated, metastatic/locally advanced, unresectable, functional or non-functional G1/G2, panNETs or midgut NETs with Ki-67 ≤20%. Patients had radiological progressive disease ≤2 years prior to study inclusion (centrally assessed) while receiving first-line LAN 120

mg at standard treatment intervals (q28d) for ≥24 weeks. Following a 28-day screening interval, LAN 120 mg was administered q14d.

RESULTS: Ninety-nine enrolled patients from 10 countries received LAN 120 mg q14d (panNET, n=48; midgut NET, n=51). In the panNET group, 22.9% and 77.1% of patients had G1 and G2 tumors (according to WHO classification), respectively; this was 54.9% and 45.1% in the midgut NET group. n/N (%) of patients with a Ki-67 of 2–10% was 28/48 (58.3%) and 18/50 (36%) in the panNET and midgut NET groups, respectively. Median (range) duration of LAN treatment (standard dosing interval) prior to study enrolment was 21.7 (5–103; panNET) and 16.4 (5–198; midgut NET) months. In the panNET group, diarrhea and flushing were present in 16.7% and 8.3% of patients; in the midgut NET group, this was 41.7% and 28.0%, respectively.

CONCLUSION: Baseline CLARINET FORTE data highlight the high rate of G1 in progressive midgut NET and of G2 in panNET. The cohort is representative of typical patients requiring treatment intensification due to progressive panNET or midgut NET. Final analyses in Q1 2020 will provide efficacy and safety data for LAN 120 mg at q14d.