Background: CLARINET is a landmark study that established the antitumour activity of LAN in patients with metastatic intestinal or pancreatic NETs. Here, we report final long-term safety data from the recently completed OLE.

Methods: Patients were eligible to take part in the OLE if they had stable disease (with LAN or placebo [PBO]) at the end of, or progressive disease (PBO group only), during the 96-week double-blind core study. All patients received open-label LAN 120 mg by deep subcutaneous injection every 28 days.

Results: In total, 89 patients were treated over the core and OLE studies (42 continued on LAN in both studies [LAN:LAN group] and 47 switched from placebo in core to LAN in OLE [PBO:LAN group]). The adverse event (AE) profile of LAN treatment during both studies is summarised in the Table. The most common class of AEs on LAN:LAN across both studies was GI events (any AE, 81%; any treatment-related AE [TRAE], 43%); among these, the most frequent were diarrhoea (any AE, 40%; any TRAE, 31%) and abdominal pain (any AE, 38%; any TRAE, 17%). On PBO:LAN in the OLE study, GI events (any AE/any TRAE) occurred in 66%/36% with diarrhoea in 32%/26% and abdominal pain in 21%/25%. Only five patients withdrew due to AEs, of which only one was treatment-related. No new safety concerns were identified.

Conclusions: LAN 120 mg treatment, over a period of up to >4 years, showed favourable safety/tolerability in patients with metastatic intestinal and pancreatic NETs. This supports the positive longer-term benefit–risk profile of LAN as an antitumour treatment, which is consistent with previous experience from shorter-term trials.

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