

204 patients randomly allocated to treatment

Core study

101 received lanreotide

103 received placebo

53 eligible for OLE study comprising:

85 eligible for OLE study comprising:

SD in core study: 53

[PD in core study:
not eligible]

SD in core study: 26

PD in core study: 59

13 did not enter OLE study:
10 – study centres not participating
3 – reason not documented

39 did not enter OLE study:
27 – study centres not participating
12 – reason not documented

41 entering OLE study in the LAN–LAN group

47 entering OLE study in the PBO–LAN group

SD in core study: 40

PD in core study: 1 (ineligible patient*)

SD in core study:
14 (+ 1 ineligible patient†)

PD in core study: 32

10 PD
0 deaths

3 PD
0 deaths

14 further PD
0 deaths

5 withdrawn due to:
1 – adverse event
1 – consent withdrawn
1 – protocol violation
2 – other reasons

Withdrawn due to ineligibility

1 withdrawn due to protocol violation
(+ 1 ineligible patient withdrawn†)

8 withdrawn due to:
1 – adverse event
4 – consent withdrawn
3 – other reasons

25 continuing in the LAN–LAN group
at time of OLE study analysis

20 continuing in the PBO–LAN group:

10 with SD in core study
continuing at time of OLE
study analysis

10 with PD in core study
continuing at time of OLE
study analysis

OLE study