

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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¹⁷⁷LU-DOTATATE PHASE 3 TRIAL IN MIDGUT NEUROENDOCRINE TUMORS

SUPPLEMENTARY APPENDIX

TABLE OF CONTENTS

Acknowledgements	2
Supplementary Table S1. Demographic and Baseline Clinical Characteristics of the Patients at Enrollment (Full Analysis Set)	3
Supplementary Table S2. ¹⁷⁷ Lu-DOTATATE Exposure.	4
Safety Assessments	6
Supplementary Figure 1. CONSORT Flow Diagram.	12
Supplementary Figure 2. Relative Change from Baseline in (a) Leukocyte Count.	13
Supplementary Figure 2. Relative Change from Baseline in (b) Lymphocyte Count.	13
Supplementary Figure 2. Relative Change from Baseline in (c) Neutrophil Count.	13
Supplementary Figure 2. Relative Change from Baseline in (d) Platelet Count.	14
Supplementary Figure 3. Creatinine Clearance Over Time in the Study.	14

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Supplementary Table S1. Demographic and Baseline Clinical Characteristics of the Patients at Enrollment (Full Analysis Set)

Characteristic	¹⁷⁷ Lu-DOTATATE (N = 116)	Octreotide LAR 60 mg (N = 113)
Gender— no. (%)		
Female	53 (46)	60 (53)
Male	63 (54)	53 (47)
Mean age (SD) — yr	63 (±9)	64 (±10)
Mean BMI (±SD) — kg/m²	25 (±5)	26 (±7)
Continent of origin— no. (%)		
USA	66 (57)	69 (61)
EU	50 (43)	44 (39)
Median time since diagnosis — yr	3.8	4.8
Mean KPS (SD)	88.6 (±9.32)	88.0 (±9.56)
Primary tumor site — no. (%)		
Jejunum	6 (5)	9 (8)
Ileum	86 (74)	82 (73)
Small intestine	11 (9)	12 (11)
Appendix	1 (1)	2 (2)
Right colon	3 (3)	1 (1)
Midgut (not otherwise specified)	9 (8)	7 (6)
Site of metastasis — no. (%)		
Liver	97 (84)	94 (83)
Lymph nodes	77 (66)	65 (58)
Mesentery	17 (15)	8 (7)
Bone	13 (11)	12 (11)
Lungs	11 (9)	5 (4)
Peritoneum	7 (6)	10 (9)
Ovaries	1 (1)	9 (8)
Other	15 (13)	10 (9)

Ki67 index — no. (%)		
Grade 1/2	76/40 (66/35)	81/32 (72/28)
SRS, Krenning scale — no. (%)[†]		
Grade 2	11 (10)	12 (11)
Grade 3	34 (29)	34 (30)
Grade 4	71 (61)	67 (59)
Median chromogranin A (quartiles) — µg/l[§]	604 (247–2626)	648 (290 – 2674)
Median 5-HIAA (quartiles)[‡] — mg/24hr[§]	36 (17-126)	44 (21-92)
Median serum alkaline phosphatase (quartiles) — U/l[§]	99 (74-160)	106 (75-152)
Previous treatments—no. (%)[*]		
Surgery	93 (80)	93 (82)
Tumor resection	90 (78)	93 (82)
Tumor ablation	6 (5)	11 (10)
Targeted therapy^{**}	19 (16)	17 (15)
Embolization[#]	18 (16)	13 (12)
Chemotherapy	11 (9)	14 (12)
Interferon	8 (7)	7 (6)
Angiogenesis inhibitor	6 (5)	2 (2)
Radiotherapy (external beam radiation)	4 (3)	6 (5)
PRRT	1 (1)	0 (0)
Investigational drug	1 (1)	1 (1)
¹³¹ I MIBG	0 (0)	2 (2)

5-HIAA denotes 5-hydroxyindoleacetic acid, BMI body mass index, PRRT peptide receptor radionuclide therapy, SD standard deviation, and SRS somatostatin receptor scintigraphy.

[†]Highest grade.

[‡]Available in 82 and 84 patients, in ¹⁷⁷Lu DOTATATE and Octreotide LAR 60 mg group, respectively

^{*}Other than somatostatin analogs (100% at study entry, inclusion criteria)

^{**}Includes everolimus, temsirolimus, sunitinib, imatinib, sorafenib, pazopanib, axitinib and gefitinib

[#]Includes chemo-embolization, radio-embolization and trans-arterial embolization

[§]Normal range: CgA, 19.4 to 98.1 µg/l; 5HIAA, 0 to 15 mg/24hrs; AP, 0 to 150 U/l.

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