



GI
connect

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Supported by an Independent Educational Grant from



MEETING SUMMARY

ECC 2015, SEPTEMBER 25TH – 29TH 2015
BY ASSOC. PROF. DR. GERALD PRAGER, VIENNA, AUSTRIA

Cancers of the Middle GI Tract

P. Ruszniewski (France)

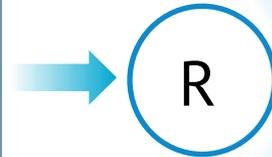
NETTER – 1 TRIAL



NETTER-1 STUDY DESIGN

- G1/G2 midgut NET
- Somatostatin receptor positive
- Failure of somatostatin analogs
- 35 US ctrs.
- 15 European ctrs

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n=230

^{177}Lu -DOTA-TYR³

7.4 GBq x 4 at 8 ± 1-week

plus supportive care with 30 mg Octreotide LAR

60 mg Octreotide LAR
(injections at 4-week intervals)

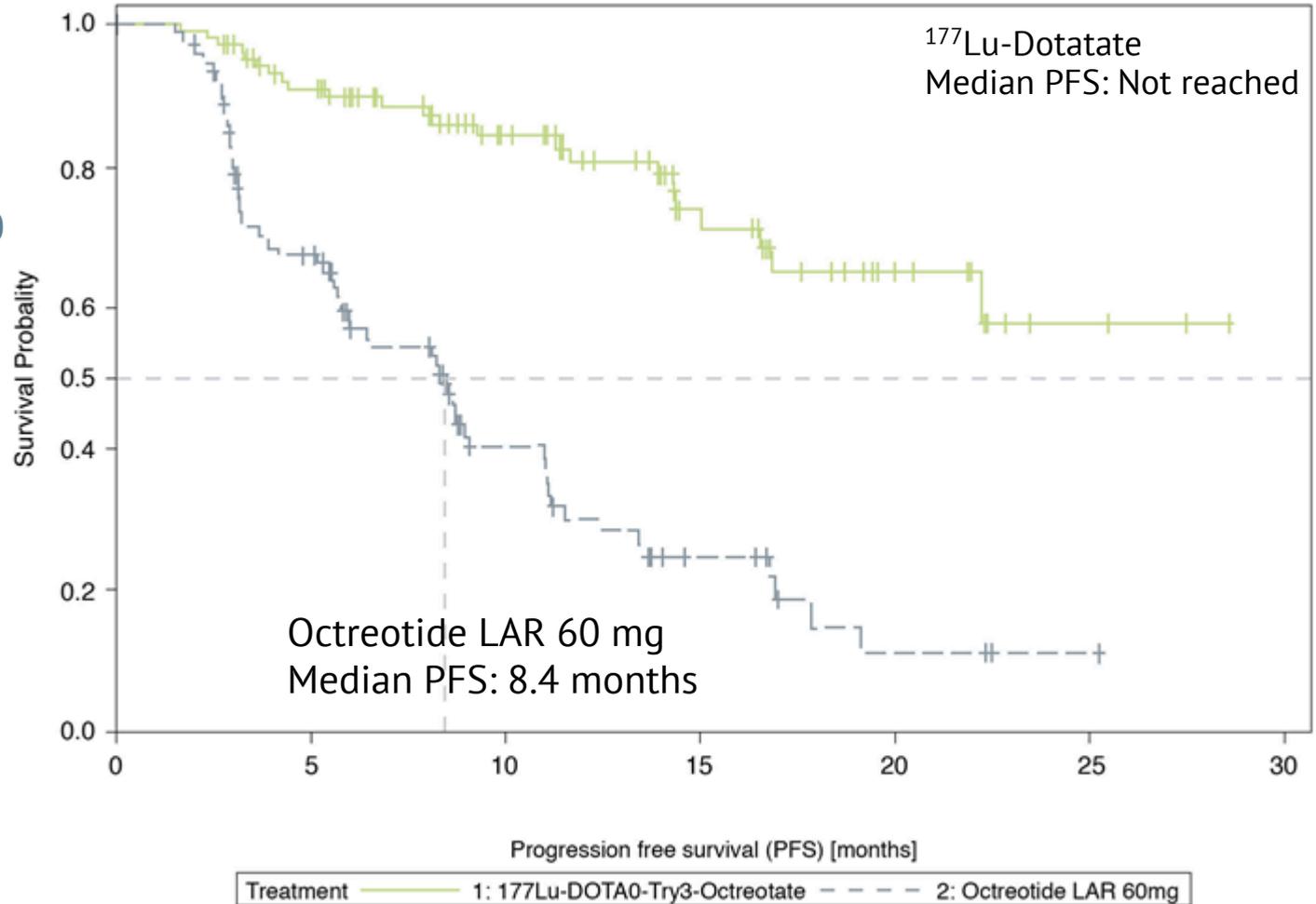
Primary endpoint Phase II (n=300): rate of complete pathological remission (pCR)

Primary endpoint for phase III (n=714): OS, HR 0.76, power 80%, two sided p<0.05

PROGRESSION FREE SURVIVAL

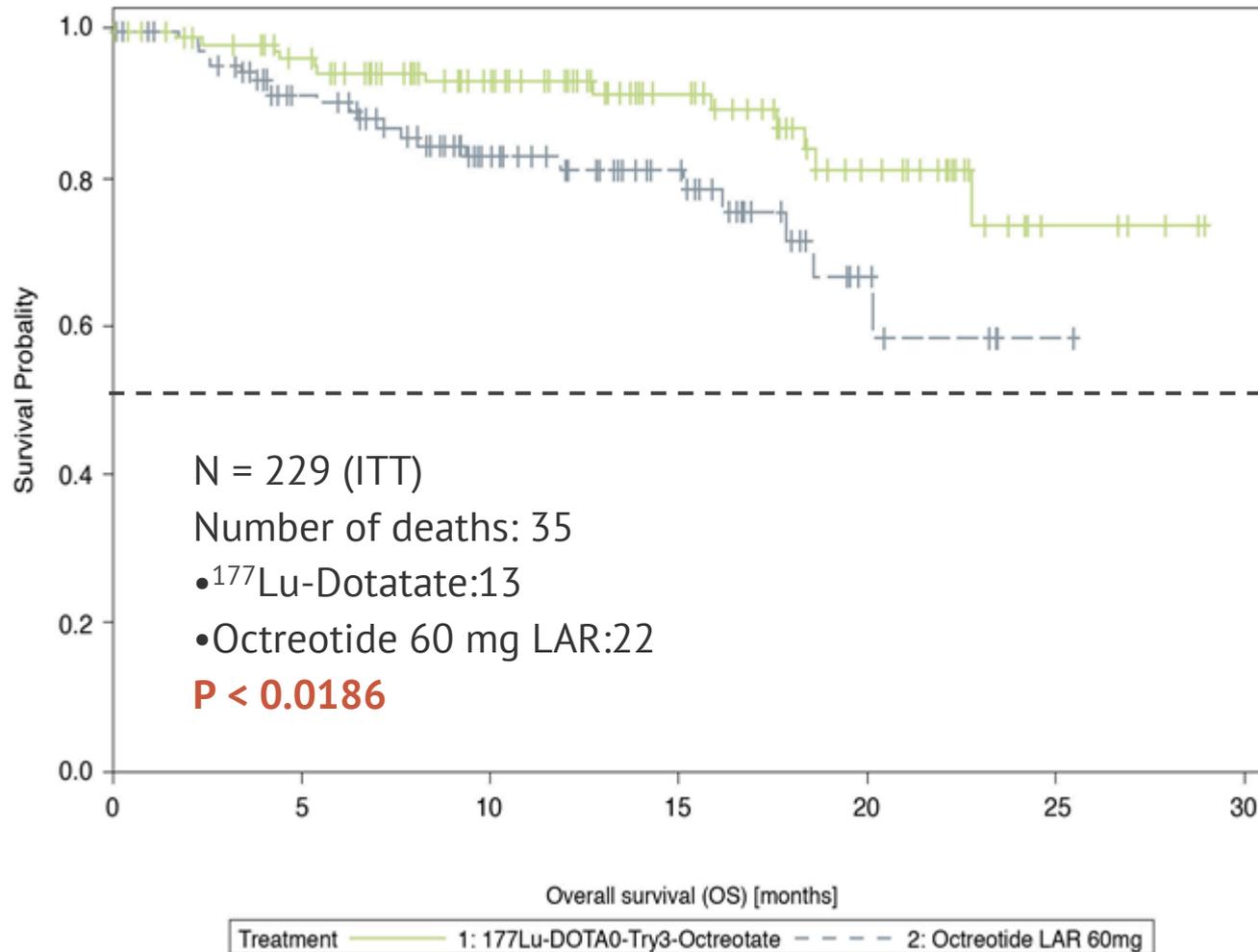
N = 229 (ITT)
Number of events: 90
•¹⁷⁷Lu-Dotatate: 23
•Oct 60 mg LAR: 67

Hazard Ratio (95% C)
0.209 (0.219 - 0.338)
p<0.0001



All progressions centrally confirmed and independently reviewed for eligibility (SAP)

OVERALL SURVIVAL (INTERIM ANALYSIS)



NETTER - 1 STUDY

	Octreotide LAR 60 mg	¹⁷⁷ Lu-DOTA-TYR3	HR
PFS	8.4 month	Not reached yet	0.21

SUMMARY AND CONCLUSIONS

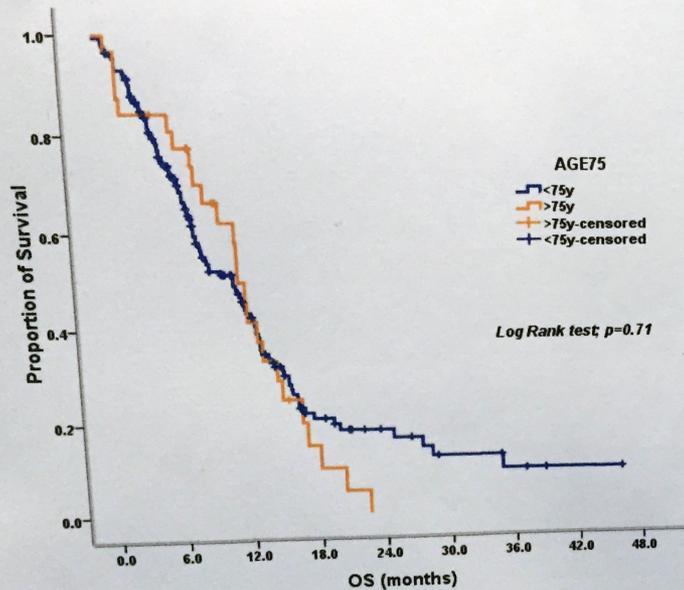
- In this first prospective randomized study in patients with progressive metastatic midgut NETs, ^{177}Lu -Dotatate was superior to Octreotide 60 mg in terms of PFS (NR vs 8.4 months, $p < 0.0001$) and ORR (19% vs 3%, $p < 0.0004$)
- Interim analysis suggests increased overall survival (13 vs 22 deaths), to be confirmed by final analysis
- Currently available safety data confirm the results of Phase I-II study, with favourable safety profile
- While few treatment options were up to now available, ^{177}Lu -Dotatate appears as a major advance in this patient population

G. Giordano (Italy)

**NAB-PACLITAXEL IN ELDERLY
AND FRAIL PATIENTS**

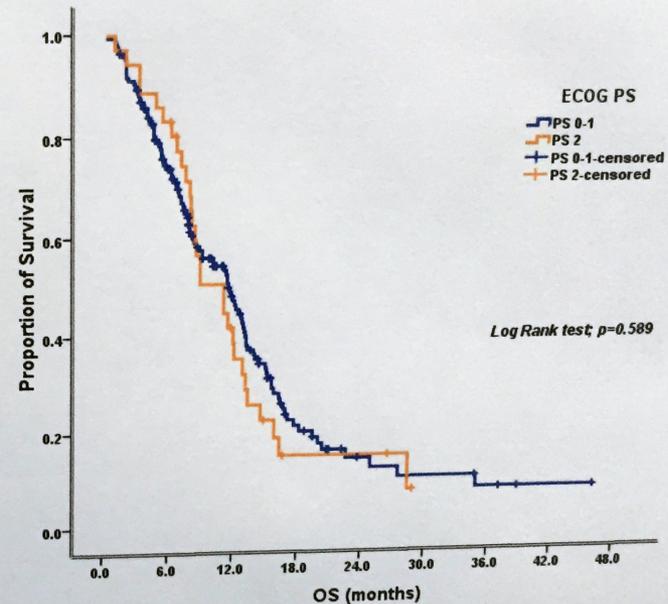
EFFICACY OF NAB-PACLITAXEL PLUS GEMCITABINE IS NOT AFFECTED BY AGE OR PERFORMANCE STATUS

Figure 1a: Kaplan Meier for OS related to age



Blue: < 75 y
Yellow: > 75 y

Figure 1b: Kaplan Meier for OS related to ECOG PS



Blue: ECOG 0-1
Yellow: ECOG 2

Age

Baseline Performance Status

MPACT-TRIAL: NAB-PALITAXEL PLUS GEMCITABOINE IMPROVES PRESERVATION OF PERFORMANCE STATUS IN MPDAC PATIENTS (E.G.CHIOREAN, USA)

