Nuevos avances en terapias dirigidas en terapias neuroendocrinas

Dr Angela Lamarca MD, PhD, MSc

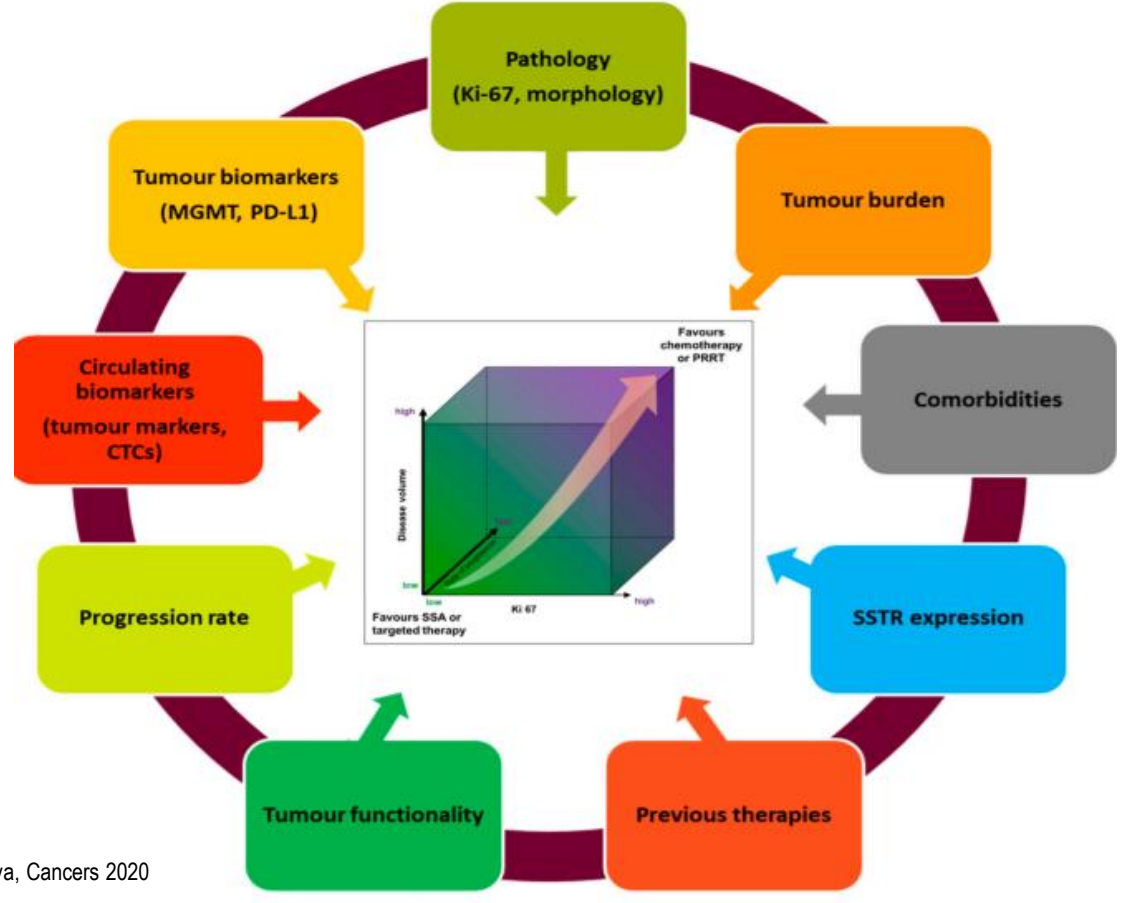
Consultant Medical Oncologist

Department of Medical Oncology, Oncohealth Institute
Instituto de Investigaciones Sanitarias
Fundación Jimenez Diaz University Hospital, Madrid, Spain

Disclosures

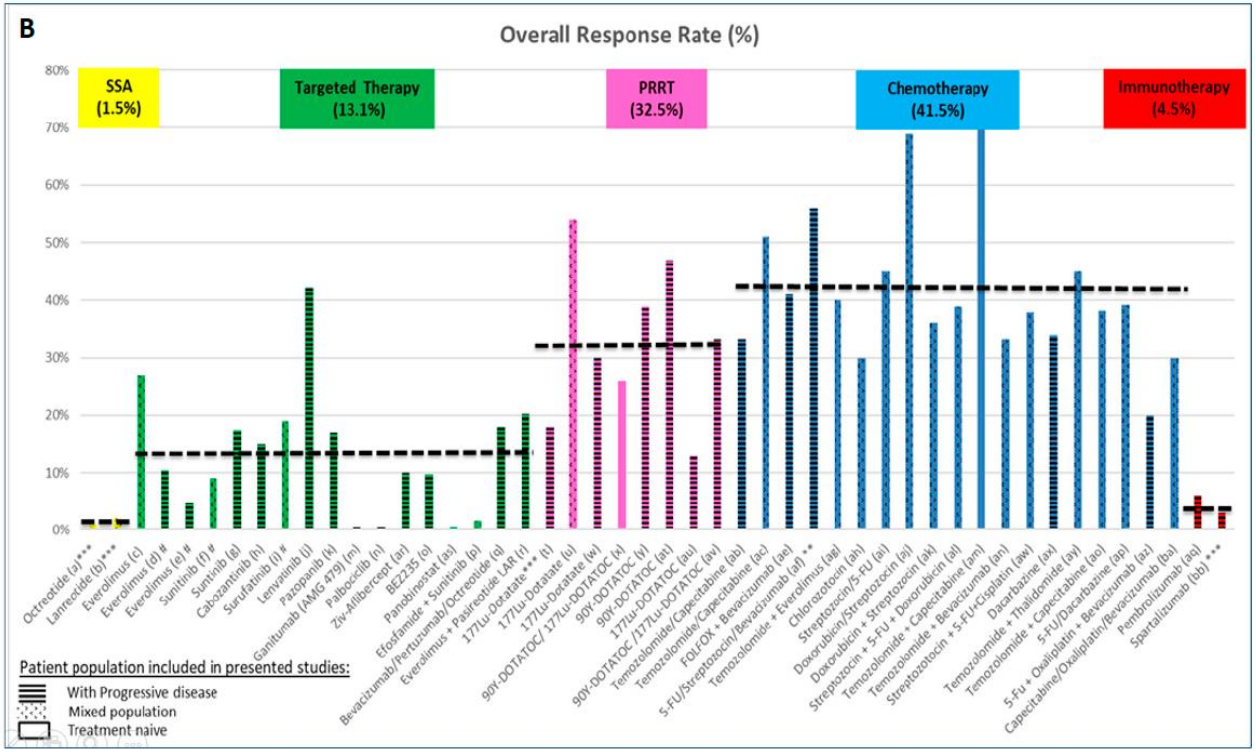
- Travel and educational support from Ipsen, Pfizer, Bayer, AAA, SirtEx, Novartis, Mylan, Delcath Advanz Pharma and Roche.
- Speaker honoraria from Merck, Pfizer, Ipsen, Incyte, AAA/Novartis, QED, Servier, Astra Zeneca, EISAI, Roche, Advanz Pharma and MSD.
- Advisory and consultancy honoraria from EISAI, Nutricia, Ipsen, QED, Roche, Servier, Boston Scientific, Albireo Pharma, AstraZeneca, Boehringer Ingelheim, GENFIT, TransThera Biosciences, Taiho and MSD.
- Principal Investigator-associated Institutional Funding form QED, Merck, Boehringer Ingelheim, Servier, Astra Zeneca, GenFit, Panbela Therapeutics, Novocure GmbH, Camurus AB, Albireo Pharma, Taiho, TransThera, JazzTherapeutics and Roche.
- Member of the Knowledge Network and NETConnect Initiatives funded by Ipsen.

Optimising treatment selection



Megdanova-Chipeva, Cancers 2020

Optimising treatment selection



Treatment options in PanNETs

Figure 1. (**A**) Graphical representation and pooled progression-free survival (PFS) and (**B**) objective response rate (ORR) by treatment group. Data for the studies summarised in Tables S1–S5 are presented. Mean PFS and ORR are calculated from studies with data available. PRRT: Peptide receptor radionuclide therapy;

Megdanova-Chipeva, Cancers 2020

Hospital Universitario Fundación Jiménez Díaz
Grupo quirónsalud
Oncohealth Institute

IIS FJD
INSTITUTO DE INVESTIGACIÓN SANITARIA
FUNDACIÓN JIMÉNEZ DÍAZ

Summary of Phase III–IV trials in NETs

Author	Phase / type	*N*	Disease	Treatment	Response (%)	TTP / PFS† (months)	OS (months)
Somatostatin analogues							
PROMID Rinke et al.[1]	IIIB	85	GEP-NET	Octreotide vs. placebo	SD at 6 months: 66.7 vs. 37.2	14.3 vs. 6 (p<0.001)	
CLARINET Caplin et al.[2]	III	204	P-NET, mid-gut, hind-gut NET	Lanreotide* vs. placebo	Rate of PFS at 24 months 65.1% vs. 33.0%	Not reached vs. 18.0 months, (p<0.001)	
PRRT							
NETTER-1 Strosberg et al.[3]	III	229	Intestinal (midgut) NET	Lutetium-177 (177Lu)–Dotatate vs. octreotide	18 vs 3 (p<0.001)	NR vs 8.4 (p<0.001)	*Data immature at time of analysis*
Targeted therapies							
SU1111 Raymond et al.[4–6]	III	171	Pancreatic NET	Sunitinib vs. placebo	ORR: 9.3 vs. 0 p=0.007	11.4† vs. 5.5† p<0.001	38.6 vs. 29.1 *p=0.094*
RADIANT-2 Pavel et al.[7]	III	429	Carcinoid	Everolimus vs. placebo		16.4† vs. 11.3† p=0.026	
RADIANT-3 Yao et al.[8]	III	410	Pancreatic NET	Everolimus vs. placebo		11.0† vs. 4.6† p<0.001	
RADIANT-4 Yao et al.[9]	III	302	Lung or GI NET	Everolimus vs. placebo	Estimated PFS rate at 12 months 44% vs. 28%	11.0 vs.3.9	
PhIV Raymond et al.[9]	IV	106	Pancreatic NET	Sunitinib	ORR: 24.5	13.2	37.8 (not yet mature)

1. Rinke A, et al. J Clin Oncol 2009;27:4656–4663; 2. Caplin N Engl J Med 2014;371:224-33.ME et al.; 3. Strosberg J, et al. N Engl J Med 2017; 376:125-135; 4. Raymond E, et al. N Engl J Med 2011;364:501–513; 5. Vinik A, et al. ASCO Meeting Abstracts 2012;30:4118; 6. Faivre S et al. Ann Oncology 2017;28:339–343; 7. Pavel ME, et al. Lancet 2011;378:2005–2012; 7. Yao JC, et al. N Engl J Med 2011;364:514–523; 8.Yao JC et al. Lancet. 2016; 387):968–977; 9. Raymond E, et al. Neuroendocrinology 2018;107:237–45.

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

- Lenvatinib
- Cabozantinib
- Surufatinib
- Axitinib

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

- **Lenvatinib**
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STUDY DESIGN

- Non-randomised phase II
- Inclusion criteria
  - Advanced NETs (G1/2) –Progressive disease to prior targeted agents
- Lenvatinib 24 mg od (progressive dose reductions (20/14/10 mg) were permitted)
- Primary end-point: Response rate (central review)

Capdevila JCO 2021

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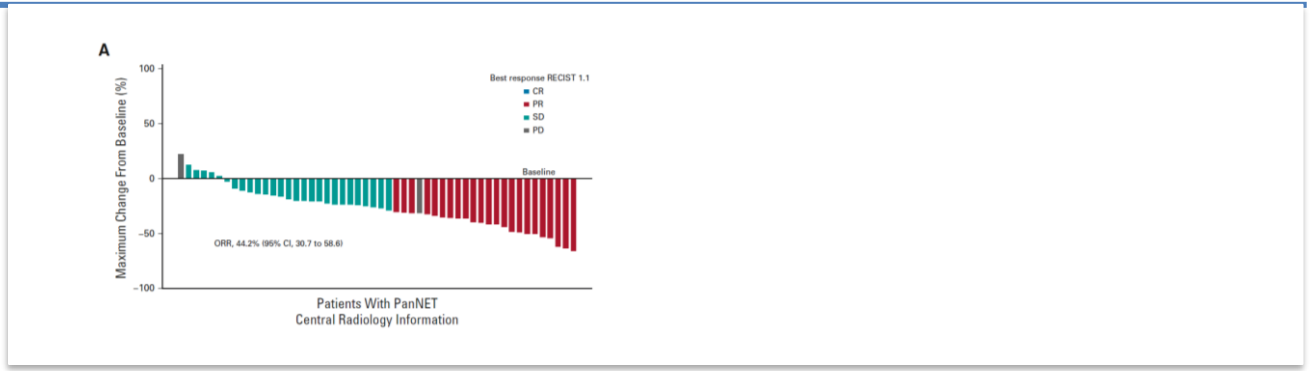

ACTIVITY

n=55 PanNETs COHORT (76.4% G2; 29% prior sunitinib; 69% prior everolimus)

- **Partial response 44.2%;** Disease control rate 96.2%
- **Duration response: median 19.9 months** (95% CI 8.4-30.8)
- **Progression-free survival: median 15.6 months** (95% CI 11.4-nr)
- Overall survival: median 32 months (95% CI 26.47-nr)

Capdevila JCO 2021

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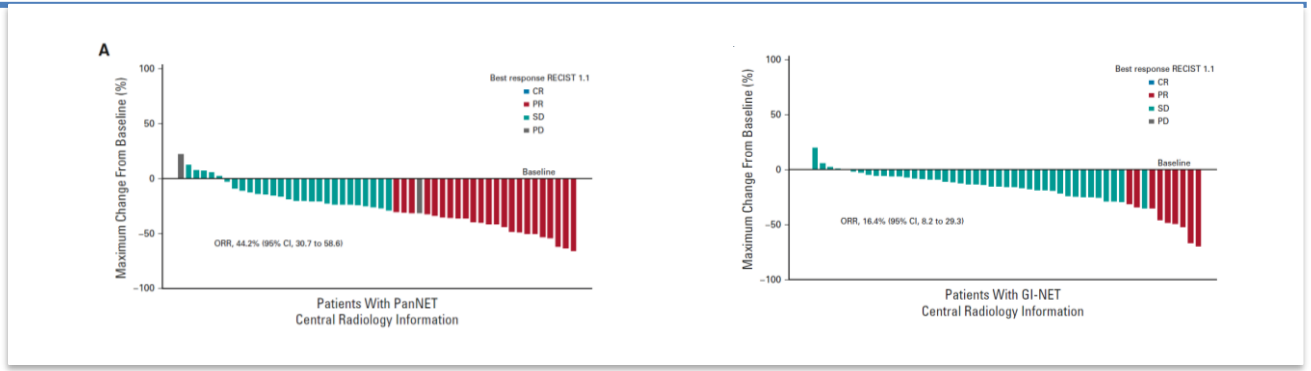

<u>ACTIVITY</u>

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- **Duration response: median 19.9 months** (95% CI 8.4-30.8)
- **Progression-free survival: median 15.6 months** (95% CI 11.4-nr)
- Overall survival: median 32 months (95% CI 26.47-nr)

n=56 Small Bowel NETs COHORT (60.7% G2; 0% prior sunitinib; 0% prior everolimus)

- **Partial response 16.4%;** Disease control rate 92.7%
- **Duration response: median 33.9 months** (95% CI 10.6-38.3)
- **Progression-free survival: median 15.7 months** (95% CI 12.1-19.5)
- Overall survival: not reached

Capdevila JCO 2021

Inhibiting angiogenesis in NETs – What is new?

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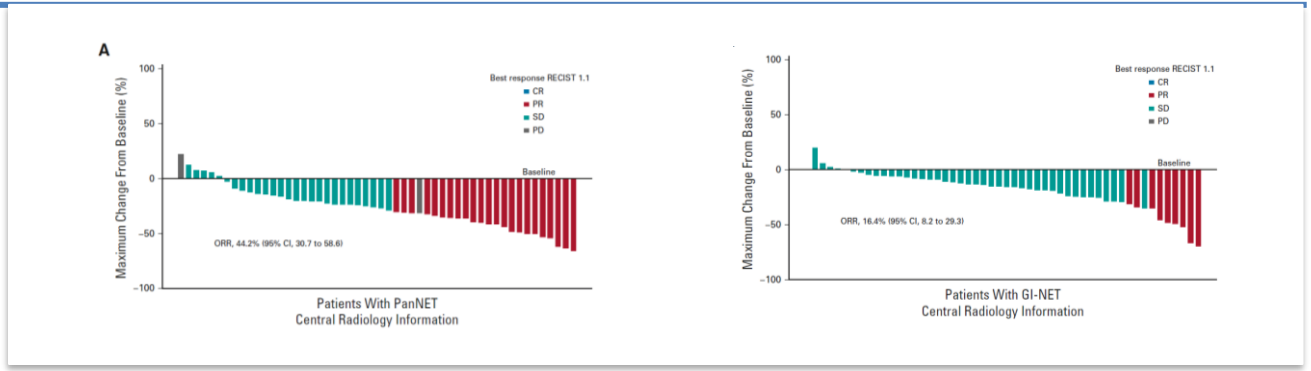

TOLERANCE

•The most common adverse events were fatigue, hypertension, and diarrhoea; 93.7% dose reductions or interruptions.

TAKE HOME MESSAGE

•Active treatment; highest centrally confirmed response reported (PanNETs!); Phase III not planned

Capdevila JCO 2021

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

- Lenvatinib
- **Cabozantinib**
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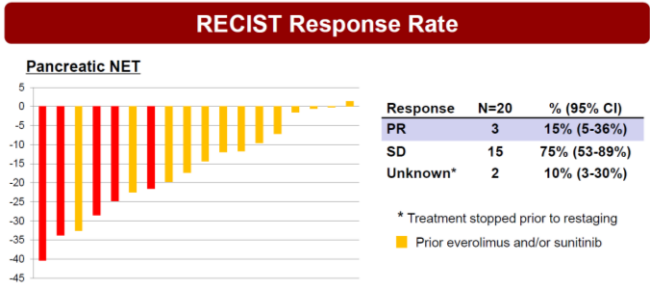
- Axitinib

STUDY DESIGN

- Non-randomised phase II
- Inclusion criteria (n=20 PanNETs)
  - Advanced well-differentiated NETs (G1/2)
  - Progressive disease within 12 months of study entry
- Cabozantinib 60 mg od
- Primary end-point: Response rate (≥3/35 required to reject H_0)

ACTIVITY AND TOLERANCE

- **Partial response 15%** (3/20 → recruitment stopped, primary objective met)
- Toxicity as expected (tolerable)



TAKE HOME MESSAGE

- CABINET trial: phase III (ongoing recruitment; NCT03375320)

Chan ENETS 2018

Inhibiting angiogenesis in NETs – What is new?

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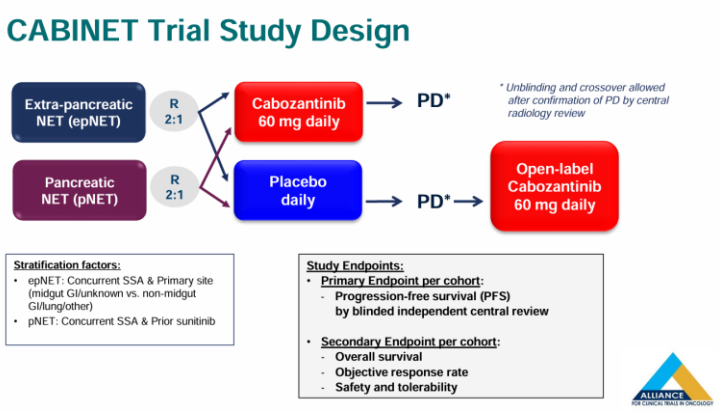
ORIGINAL ARTICLE

Phase 3 Trial of Cabozantinib to Treat Advanced Neuroendocrine Tumors

Jennifer A. Chan, M.D., M.P.H., Susan Geyer, Ph.D., Tyler Zemla, M.S.,



STUDY DESIGN

- Non-randomised phase III
- Two separate cohorts
  - Pancreatic (n=95)
  - Non-pancreatic (n=203)
  - Progressive to prior PRRT/everolimus/both
- Cabozantinib 60 mg od or placebo (2:1)
- Primary end-point: PFS (blinded central review)

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Extrapancreatic NET Cohort		Pancreatic NET Cohort	
	Cabozantinib (N=134)	Placebo (N=69)	Cabozantinib (N=64)	Placebo (N=31)
Median age (range) — yr	66 (28–86)	66 (30–82)	60 (29–79)	64 (39–79)
Female sex — no. (%)	74 (55)	31 (45)	27 (42)	13 (42)
ECOG performance-status score — no. (%)†				
0	49 (37)	32 (46)	35 (55)	15 (48)
1	84 (63)	36 (52)	28 (44)	16 (52)
Primary tumor site — no. (%)‡				
Gastrointestinal	70 (52)	46 (67)	2 (3)	1 (3)
Lung	27 (20)	12 (17)	NA	NA
Thymus	6 (4)	4 (6)	NA	NA
Pancreas	4 (3)	3 (4)	62 (97)	30 (97)
Other	5 (4)	2 (3)	NA	NA
Unknown	22 (16)	2 (3)	NA	NA

Chan NEJM 2024

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

- Lenvatinib
- **Cabozantinib**
- Surufatinib
- Axitinib

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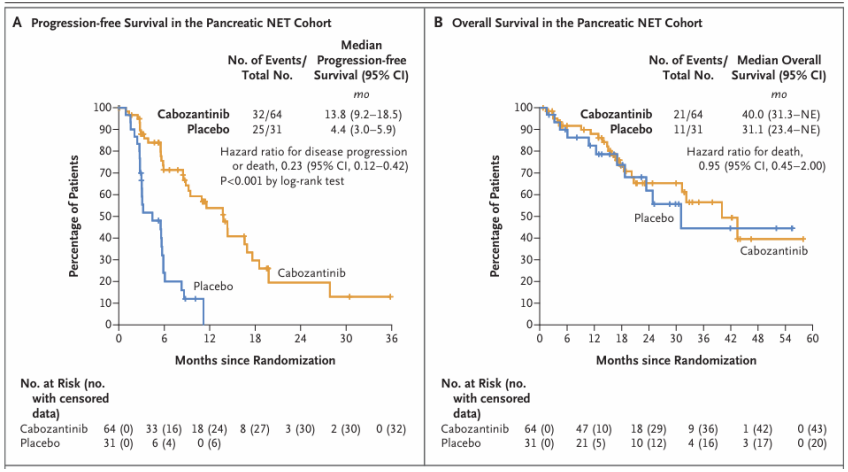

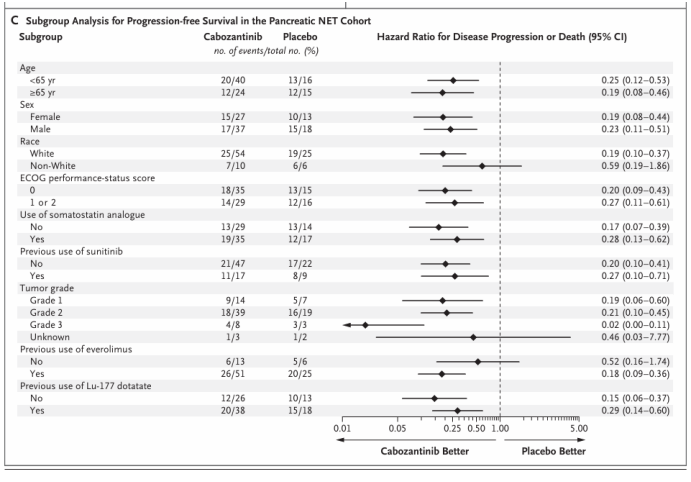

Chan NEJM 2024

Inhibiting angiogenesis in NETs – What is new?

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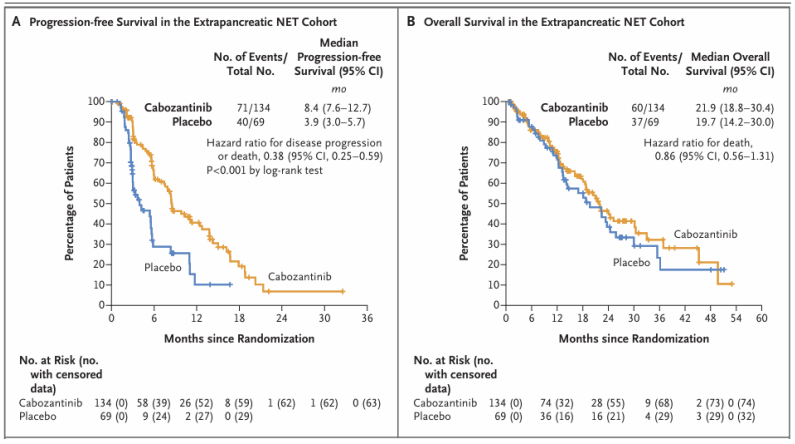

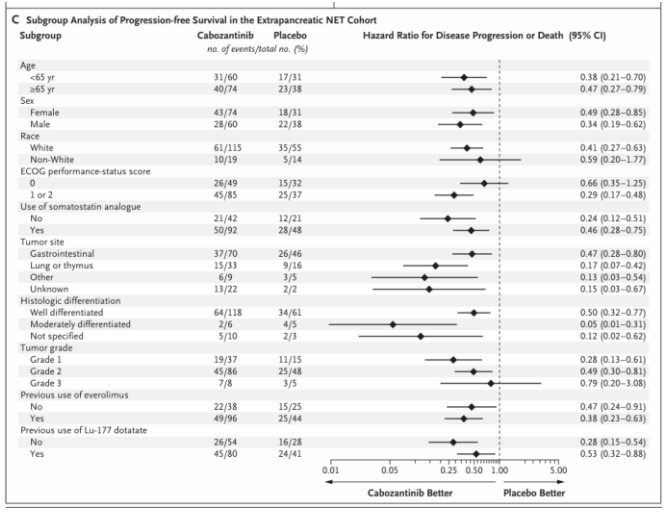

Chan NEJM 2024

Inhibiting angiogenesis in NETs – What is new?

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STUDY DESIGN

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- Two separate cohorts
  - Pancreatic (n=95)
  - Non-pancreatic (n=203)
  - Progressive to prior PRRT/everolimus/both
- Cabozantinib 60 mg od or placebo (2:1)
- Primary end-point: PFS (blinded central review)

Table 2. Objective Tumor Response.*

Response	Extrapancreatic NET Cohort		Pancreatic NET Cohort	
	Cabozantinib (N=134)	Placebo (N=69)	Cabozantinib (N=64)	Placebo (N=31)
Objective response — % (95% CI)	5 (2 to 10)	0 (0 to 5)	19 (10 to 30)	0 (0 to 11)
Best overall response — no. (%)				
Partial response	7 (5)	0	12 (19)	0
Stable disease	87 (65)	37 (54)	39 (61)	17 (55)
Progressive disease	15 (11)	24 (35)	5 (8)	12 (39)
Not evaluable	25 (19)	8 (12)	8 (12)	2 (6)

Chan NEJM 2024

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

- Lenvatinib
- Cabozantinib
- **Surufatinib**
- Axitinib

STUDY DESIGN

- Randomised phase III (surufatinib vs placebo; 2:1), China
- Inclusion criteria (PanNETs and ExtraPanNETs cohorts)
  - Advanced well-differentiated NETs (G1/2) Progressive disease on up to two kinds of previous systemic regimens for advanced disease
- Cabozantinib 300 mg od
- Primary end-point: PFS (investigator-assessed)

Xu Lancet Oncol 2020; Xu Lancet Oncol 2020

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

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- Cabozantinib
- **Surufatinib**
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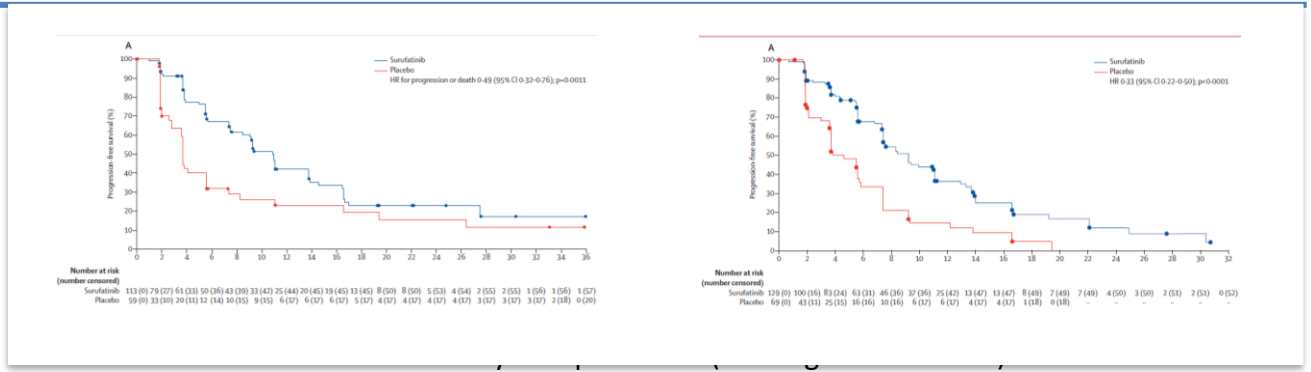

ACTIVITY AND TOLERANCE

n=172 PanNETs COHORT (88%-85% G2)

- Recruitment stopped due to activity (IDMC): **PFS: primary end-point met** (10.9 months (7.5–13.8) vs 3.7 months (2.8–5.6)); **HR 0.49 (95% CI 0.32-0.76); p-value 0.0011** (central review: HR 0.34 (95% CI 0.21-0.55; p-value < 0.0001)
- **Partial Response 19%**

Xu Lancet Oncol 2020; Xu Lancet Oncol 2020

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

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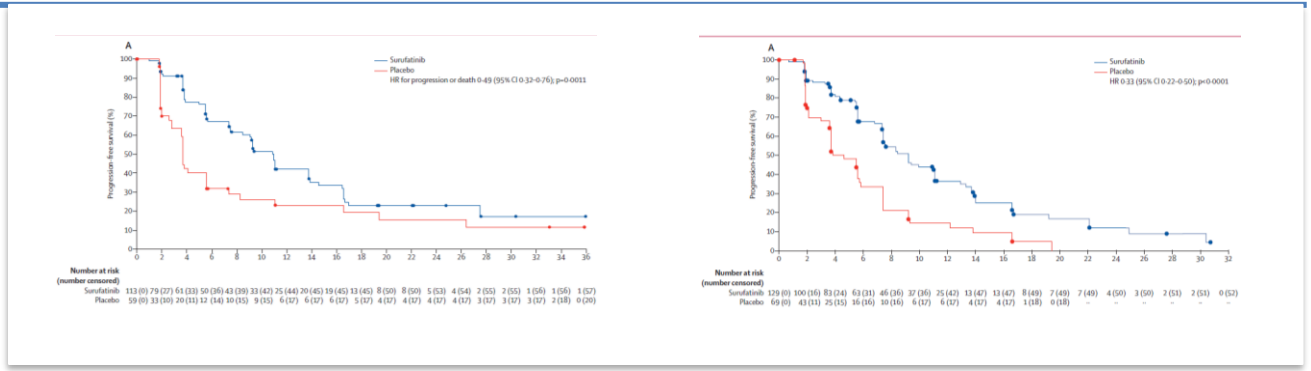

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- **Partial Response 19%**

n=198 ExtraPanNETs COHORT (84%-84% G2)

- Recruitment stopped due to activity (IDMC): **PFS: primary end-point met** (9.2 months (7.4–11.1) vs 3.8 months (3.7–5.7)); **HR 0.33 (95% CI 0.22-0.50); p-value <0.0011**
- **Partial Response 10%**

TAKE HOME MESSAGE

- New treatment option (China?)
- Ongoing phase II in Europe (NCT04579679)

Xu Lancet Oncol 2020; Xu Lancet Oncol 2020

Inhibiting angiogenesis in NETs – What is new?

New TKIs:

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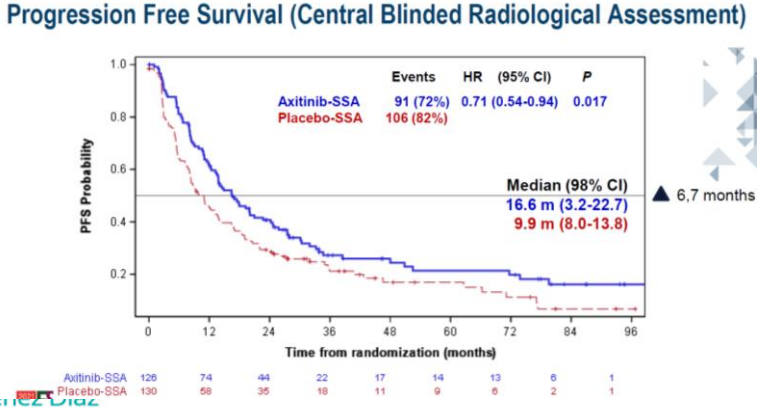


Garcia-Carbonero ASCO-GI 2021; Garcia-Carbonero ESMO 2021

STUDY DESIGN

- Randomised phase II/III (octreotide+axitinib vs octreotide+placebo)
- Inclusion criteria (n=256 extra-PanNETs)
  - Primary tumor site GI (40%)-Lung (17%)-Other (32%).
  - Prior therapies included: SSA (46%), everolimus (13%), chemotherapy (13%), TACE (5%) and PRRT (2%).
- Axitinib 5 mg bd
- Primary end-point: PFS (investigator-assessed)

ACTIVITY AND TOLERANCE

- PFS per investigator assessment favored axitinib vs placebo-treated patients, although the difference did not reach statistical significance (median PFS 17.2 vs 12.3 months, respectively, **HR 0.816, p = 0.169**).
- ORR was significantly higher in axitinib- vs placebo-treated patients (**17.5% vs 3.8%, p = 0.0004**).

- **Update PFS data (central-review): 16.6 vs 9.9 months; HR 0.71 (95% CI 0.54-0.94); p-value 0.017**
- Updated ORR (**13.2% vs 3.2%, p = 0.0045**).

TAKE HOME MESSAGE

- Improvement on PFS and response rate: new treatment option?

Inhibiting angiogenesis in NETs – What is new?

1. New TKIs:
   - **Lenvatinib**
   - **Cabozantinib**
   - **Surufatinib**
   - **Axitinib**

- ✓ None approved yet
- ✓ Activity for cabozantinib and surufatinib confirmed in phase III studies
- ✓ Lenvatinib: highest ORR in PanNETs

The question is….

- Is angiogenesis inhibition **superior to other options** in NETs ?

The question is….

- Is angiogenesis inhibition **superior to other options** in NETs ?

vs Everolimus?
vs PRRT?
vs Chemotherapy?

Is angiogenesis inhibition superior to other options?

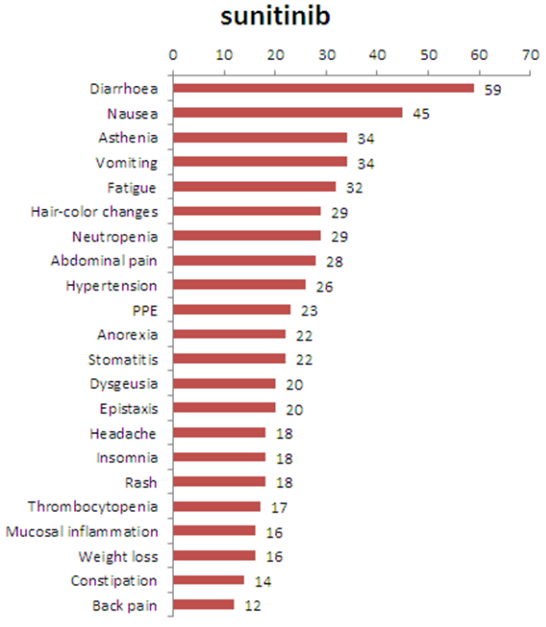
- It has not been compared to other strategies (trials vs placebo)

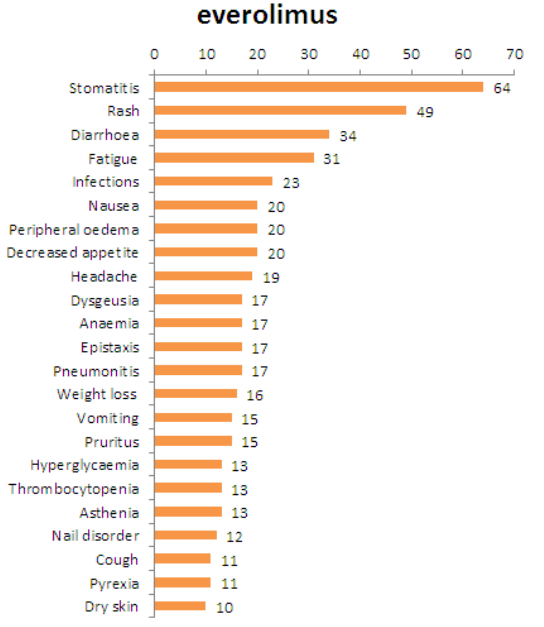
	Sunitinib 37.5 mg once daily (Phase III vs placebo)	Everolimus 10 mg once daily (Phase III vs placebo)
Population of patients	Unresectable or metastatic, well- or moderately-differentiated **PanNETs**	Unresectable or metastatic, well- or moderately-differentiated **PanNETs**
Documented disease progression at study entry	Yes	Yes
Objective response rate	9.3% vs 0%	5% vs 2%
Median PFS (experiment vs placebo) (months)	11.4 vs 5.5 HR 0.42 (95% CI 0.26-0.66); p-value <0.001.	11.0 vs 4.6 HR 0.35 (95% CI 0.27-0.45); p-value <0.001.
Comments	AEs: increased blood pressure Patients benefit regardless of prior chemotherapy use. Benefit regardless of tumour burden.	AEs: hyperglycaemia Patients benefit regardless of prior chemotherapy use. Benefit regardless of tumour burden.

Yao NEJM 2011; Raymond NEJM 2011; Lombard-Bohas Pancreas 2015

Not “superior” but yes “different” - Toxicity

- All-Grade toxicities in registration studies (panNET)





Note – this is a crosstrial comparison from two different studies for illustration only

1. Raymond et al NEJM 2011;364:501–13; 2. Yao et al NEJM 2011;364:514–23.

Not “superior” but yes “different” - Toxicity

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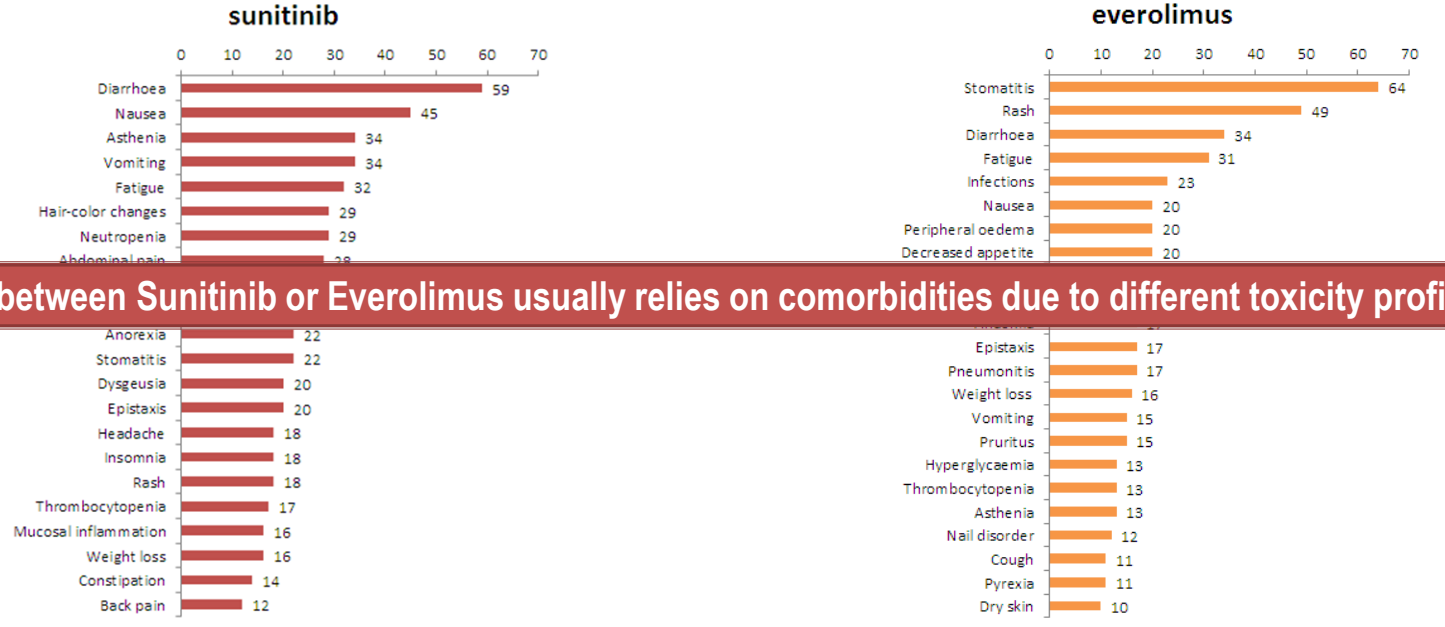


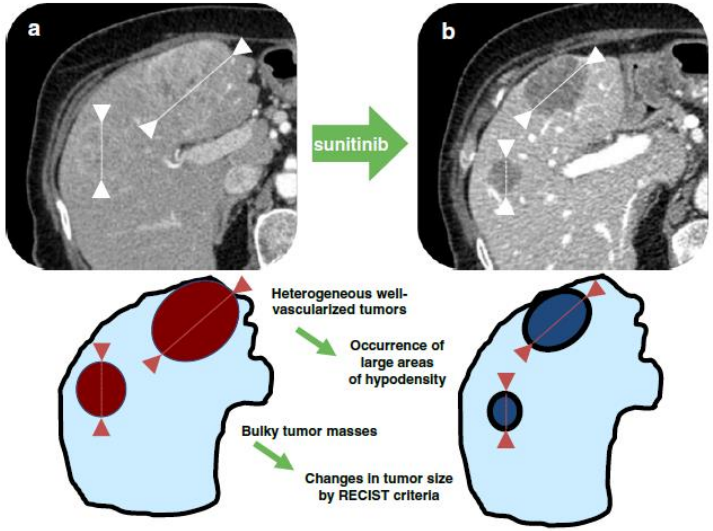
Selection between Sunitinib or Everolimus usually relies on comorbidities due to different toxicity profile

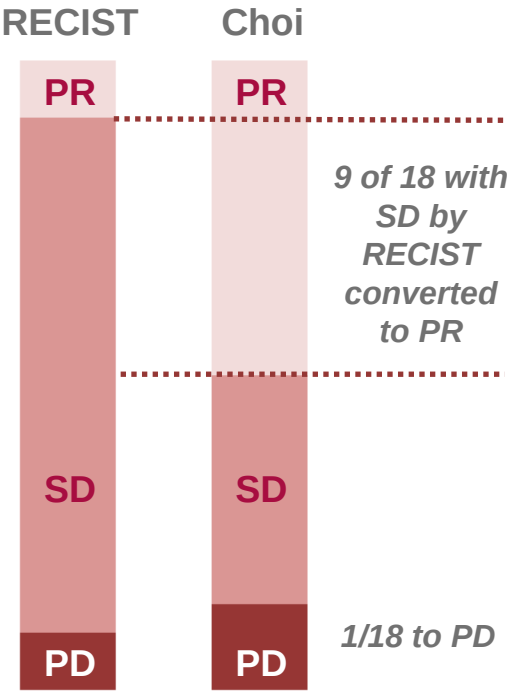
Note – this is a crosstrial comparison from two different studies for illustration only

1. Raymond et al NEJM 2011;364:501–13; 2. Yao et al NEJM 2011;364:514–23.

Not “superior” but yes “different” - Response assessment

- Changes in size (RECIST) vs tumour density (Choi)





Median TTP: PR: 26.1 mo | **SD:** 8.7 mo | **PD:** 3.6 mo; p=0.038

Cystic changes are reflection of response. Do not confound with progression.

PD, progressive disease; PR, partial response; SD, stable disease.
Faivre, et al. *Target Oncol* 2012 Jun;7(2):127-33.

Not “superior” but yes “different” - Response assessment

- Changes in size (RECIST) vs tumour density (Choi)

A meaningful number of patients classified as stable disease by RECIST were reclassified as responders
(26/44=59%)

All patients classified as partial response by RECIST were classified as responders
(10/100=100%)

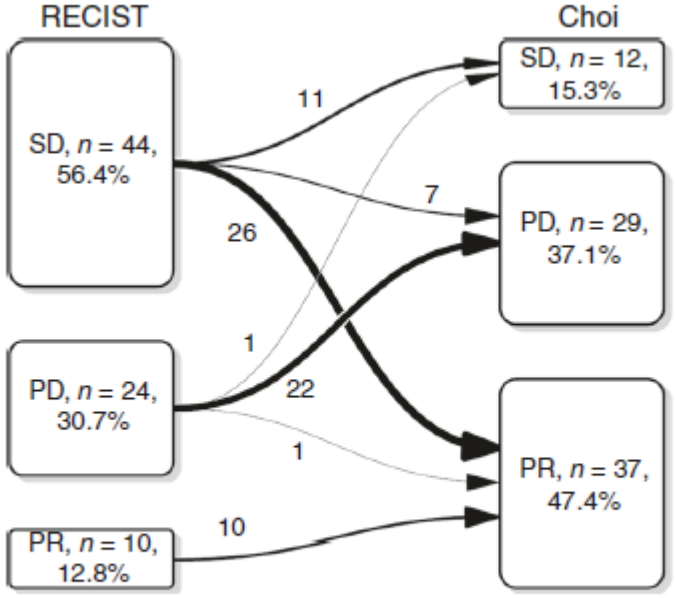


Fig. 2 Transition plot with the reclassification between RECISTv1.1 and Choi criteria. n number, PD progressive disease, PR partial response, SD stable disease

Solis Hernandez, BJC 2019

Not “superior” but yes “different” - Response assessment

- Changes in size (RECIST) vs tumour density (Choi)

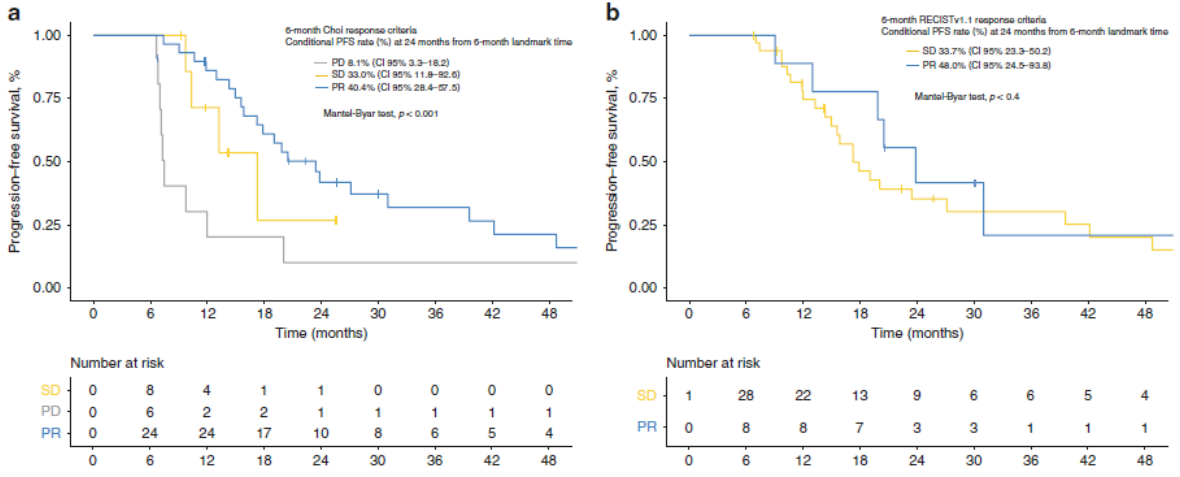


Fig. 3 **a** Kaplan–Meier curves for conditional progression-free survival from 6-month landmark time stratified by Choi. **b** Kaplan–Meier curves for conditional progression-free survival from 6-month landmark time by RECIST. It does not include the PD category by RECIST as it coincides with the endpoint. CI confidence interval, PD progressive disease, PFS progression-free survival, PR partial response, SD stable disease

Choi (Figure A) predicted PFS more accurately than RECIST (Figure B)

Solis Hernandez, BJC 2019

Not “superior” but yes “different” - Response assessment

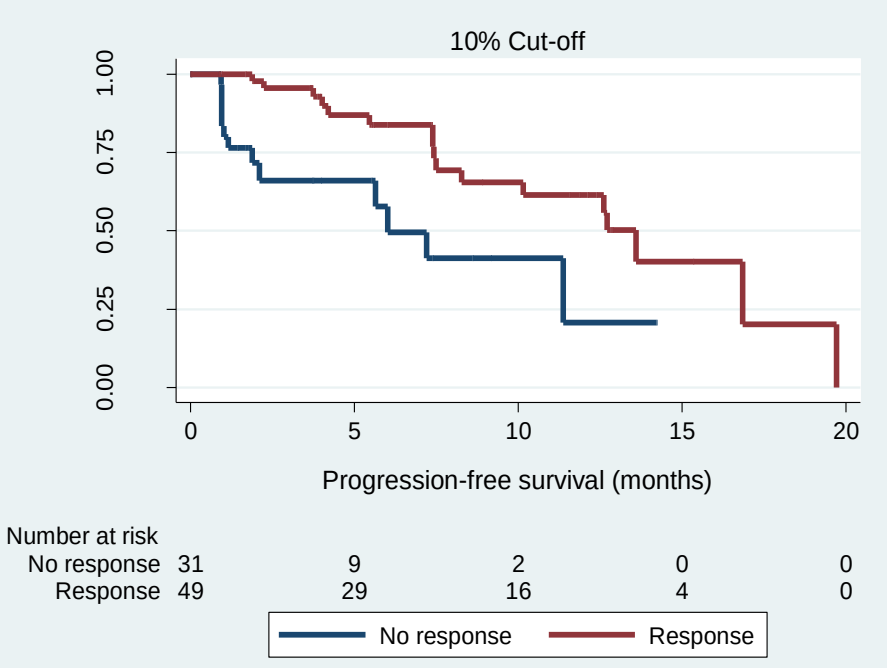
- Relevance of tumour regression even if Partial Response not met

Reduction of **10%** (vs baseline) achieved the highest sensitivity (50%) and specificity (82%)

A 10% reduction in marker lesions was associated with improved PFS in the whole sunitinib population

A 10% reduction in marker lesions and sunitinib treatment independently impacted on PFS

A 10% reduction within marker lesions identifies patients benefiting from sunitinib treatment



Lamarca BJC 2017

The question is….

- Is angiogenesis inhibition **superior to other options** in NETs ?

vs Lenvatinib?
vs PRRT?
vs Chemotherapy?

Taregted vs PRRT?

Optimising management of GEP-NETs

- No comparative studies

	Targeted therapies	PRRT
Target	Systemic	Systemic
SSTR	–ve and +ve	+ve
Functioning	Both (No > Yes)	Both
Response	Early response	Later response
Logistics	Quick(er)	Late(ish)

The question is….

- Is angiogenesis inhibition **superior to other options** in NETs ?

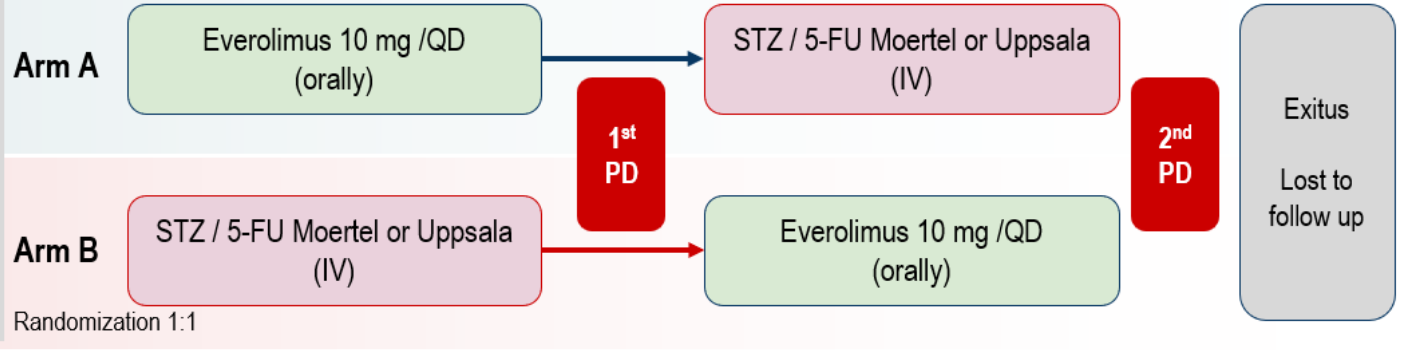
vs Lenvatinib?
vs PRRT?
vs Chemotherapy?

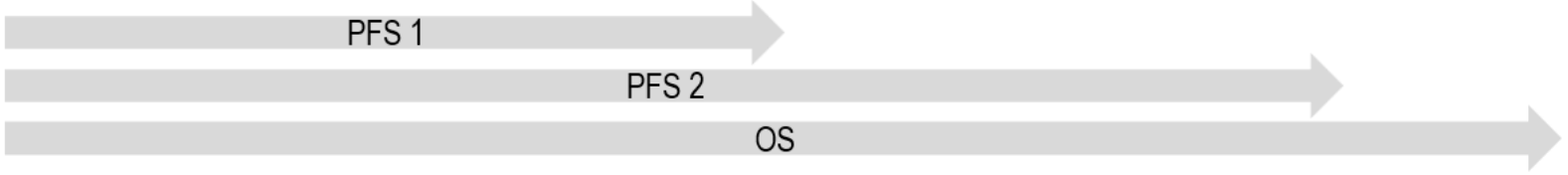
SEQTOR: EVE → CHEMO OR VICEVERSA?

Study Design

Primary endpoint (amended due to slow recruitment*): **PFS to 1st treatment (PFS1) at 12 months (m).** Secondary endpoints included objective response rate (ORR), clinical benefit rate (CBR), median PFS1 (mPFS1) and PFS to 2nd treatment (PFS2), overall survival (OS), safety and correlatives studies. Tumor imaging for this analysis were locally assessed.

- Advanced G1-G2 pancreatic NET
- Measurable disease (RECIST v1.0)
- PS 0-2
- Prior SSA allowed
- No prior chemo, mTORi, TKIs





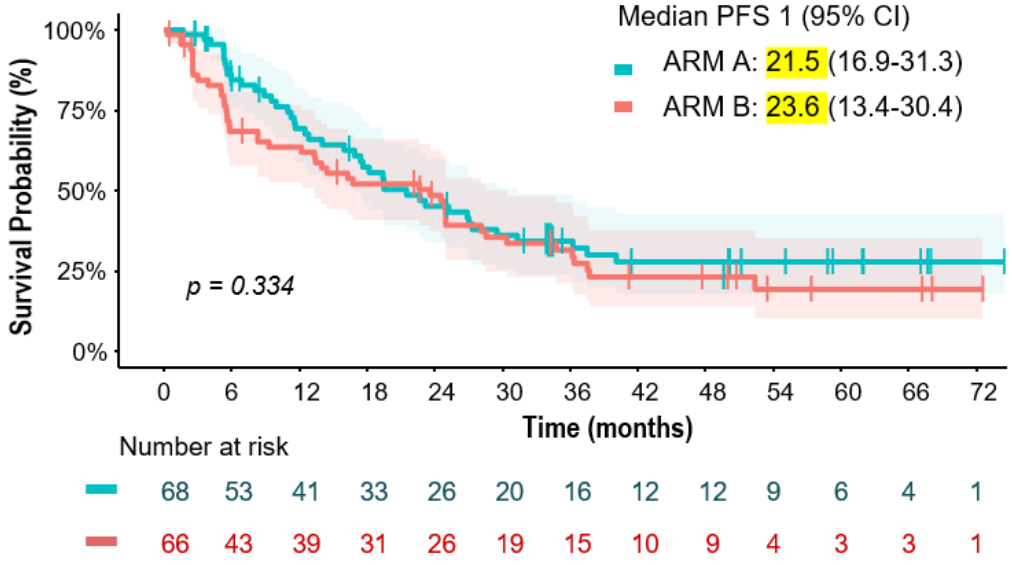
* *Study was initially designed and sized for primary endpoint PFS2 at 35 months*

Salazar, ESMO 2022

SEQTOR: EVE → CHEMO OR VICEVERSA?

Efficacy Outcomes: PFS1

The median Follow-up was 35.7 m (95%CI: 28.3-39.5)



PFS 1 rate; m (95% CI)	Arm A N = 68	ARM B N = 66
12 m	69.3 (58.7-81-9)	63.5 (52.7-76.6)
24 m	45.2 (34.1-59.8)	48.5 (37.5-62.8)
36 m	34.3 (24-49.1)	31.5 (21.4-53.9)

Salazar, ESMO 2022

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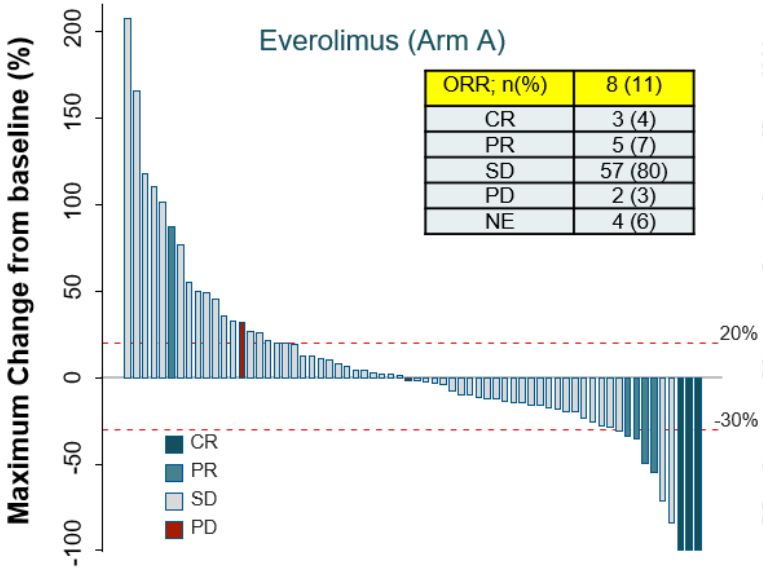
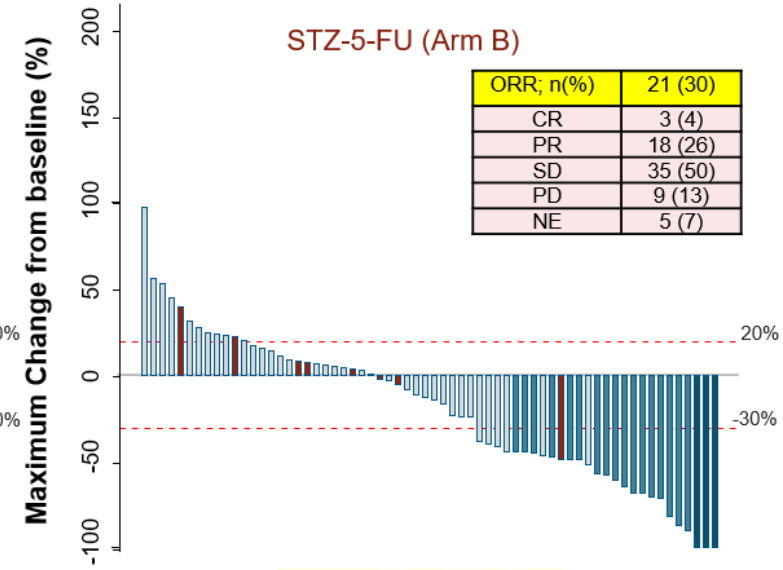
GETNE
Grupo Español de Tumores Neuroendocrinos y Endocrinos

Efficacy Outcomes: ORR to 1st treatment



ORR; n(%)	8 (11)
CR	3 (4)
PR	5 (7)
SD	57 (80)
PD	2 (3)
NE	4 (6)



ORR; n(%)	21 (30)
CR	3 (4)
PR	18 (26)
SD	35 (50)
PD	9 (13)
NE	5 (7)

Stable Disease was the most common outcome to the 1st treatment with a CBR of 92% and 80% for arms A/B, respectively (*p=0.07*)

Hospital Universitario Fundación Jiménez Díaz
Grupo quirónsalud
Oncohealth Institute

Salazar, ESMO 2022

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INSTITUTO DE INVESTIGACIÓN SANITARIA FUNDACIÓN JIMÉNEZ DÍAZ

SEQTOR: EVE → CHEMO OR VICEVERSA?

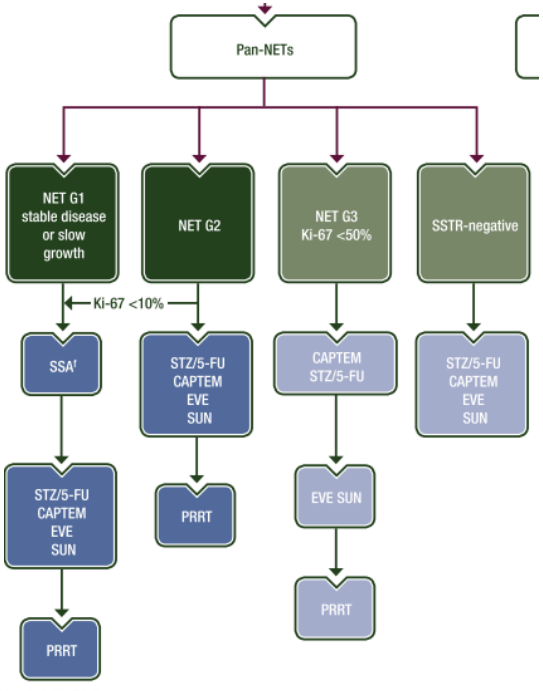
CONCLUSIONS

- Both sequential strategies showed similar efficacy, with no significant differences in PFS1.
- STZ-5FU assigned as the 1st treatment achieved a statistically significant higher ORR than everolimus, suggesting STZ-5FU should be the 1st option when tumor shrinkage is a priority.
- The differences in safety profile may also inform treatment choice for selected pts.
- Final analysis on secondary objectives, predictive translational transcriptomic and pharmacoeconomic studies, QoL and central tumor imaging review are underway.

EudraCT: 2013-000726-66 // Clinical Trial identifier: NCT02246127

ESMO vs ENETS Pan-NETs (Advanced stage)

ESMO



ENETS

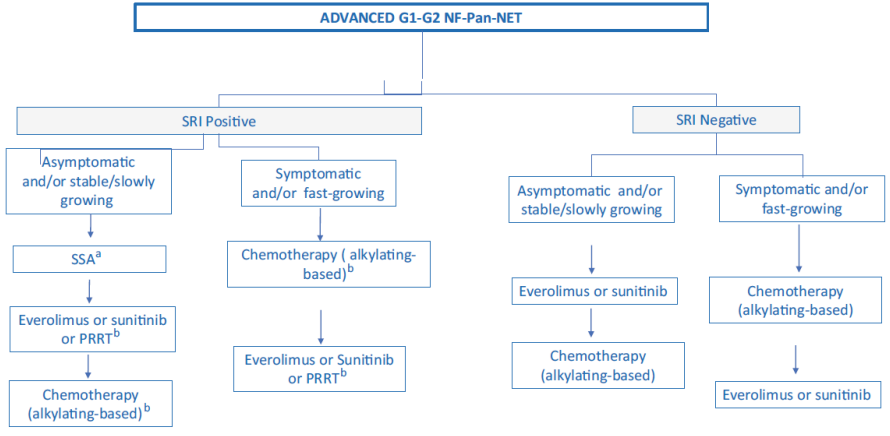
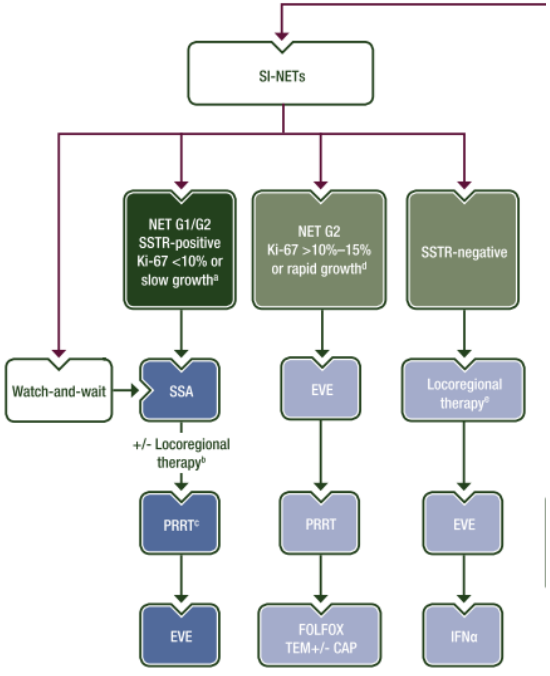


FIGURE 1 The proposed algorithm of G1-2 nonfunctioning pancreatic neuroendocrine tumours treatment. [a]Preferably for Ki 67 < 10%. [b]PRRT or chemotherapy or TAE/other liver directed therapy if cytoreductive intent.

Pavel, Annals of Oncology 2020; Kos Kudla et al, J of Neuroendocrinology 2022

ESMO vs ENETS Si-NETs (Advanced stage)

ESMO



ENETS

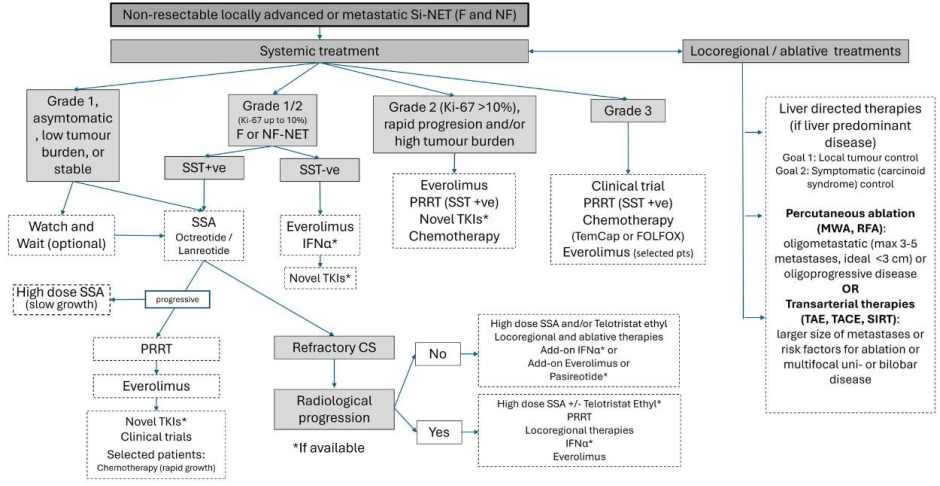


FIGURE 4 Treatment planning for Si-NET (part 2).

Pavel, Annals of Oncology 2020; Lamarca et al J of Endocrinology 2024

Take-home messages

- Targeted therapies remain a key part of management of NETs
- New therapies coming in the fields – specially targeting angiogenesis

- Patient selection in the setting of a multidisciplinary setting remains key

- Combination of targeted with other treatment options?

Thank you for your attention

Angela.Lamarca@quironsalud.es

@DrAngelaLamarca

Hospital Universitario Fundación Jiménez Díaz
Grupo quirónsalud
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