

# Interim Analysis Results of Surufatinib in US Patients with Neuroendocrine Tumors (NETs)

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## INTRODUCTION

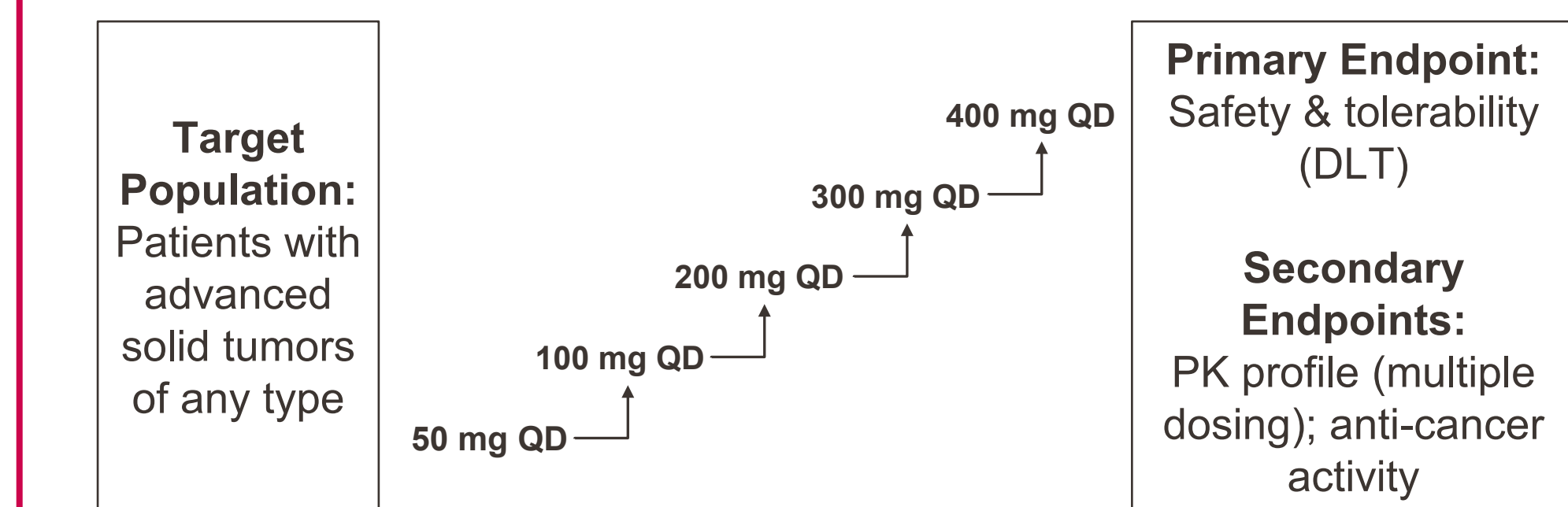
- Surufatinib is a targeted inhibitor of tyrosine kinases VEGFR1,2, and 3; FGFR1; and CSF-1R
- A manageable safety profile and statistically significant efficacy of surufatinib have previously been demonstrated in patients (pts) with advanced NETs of extrapancreatic (epNET) and pancreatic (pNET) origin in 2 phase 3 randomized trials conducted in China
- SANET-ep, NCT02588170; SANET-p, NCT02589821
- Pts with epNETs achieved a median progression free survival (PFS) of 9.2 vs 3.8 months (hazard ratio [HR] 0.334; p<0.0001), with surufatinib vs placebo, respectively
- Pts with pNETs achieved a median PFS of 10.9 vs 3.7 months (HR 0.491; p=0.0011), with surufatinib vs placebo, respectively
- Surufatinib has recently been approved for the treatment of pts with epNETs and is under review for pts with pNETs in China
- A New Drug Application has been submitted to the US FDA for review

## METHODS

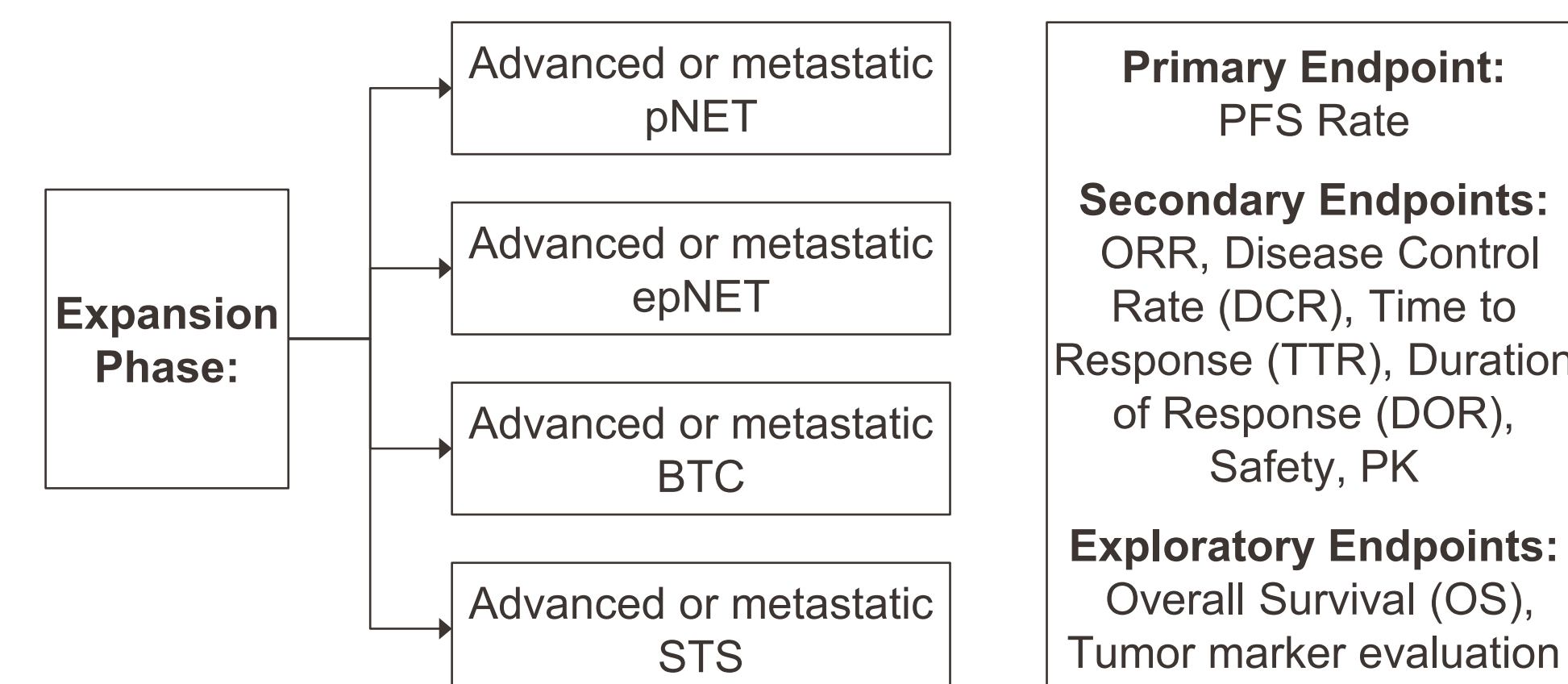
- A phase 1, Dose Escalation and Dose Expansion trial was conducted to evaluate and confirm the efficacy and safety of surufatinib in US pts
- Dose Escalation was completed, and the maximum tolerated dose (MTD) and recommend phase 2 dose (RP2D) were determined to be 300 mg, the same as previous trials
- The Dose Expansion completed enrollment of the epNET and pNET cohorts
- The primary endpoint was investigator-assessed PFS rate at 11 months
- Secondary objectives included assessment of safety and pharmacokinetics (PK) of surufatinib

## STUDY DESIGN

### Dose Escalation



### Dose Expansion



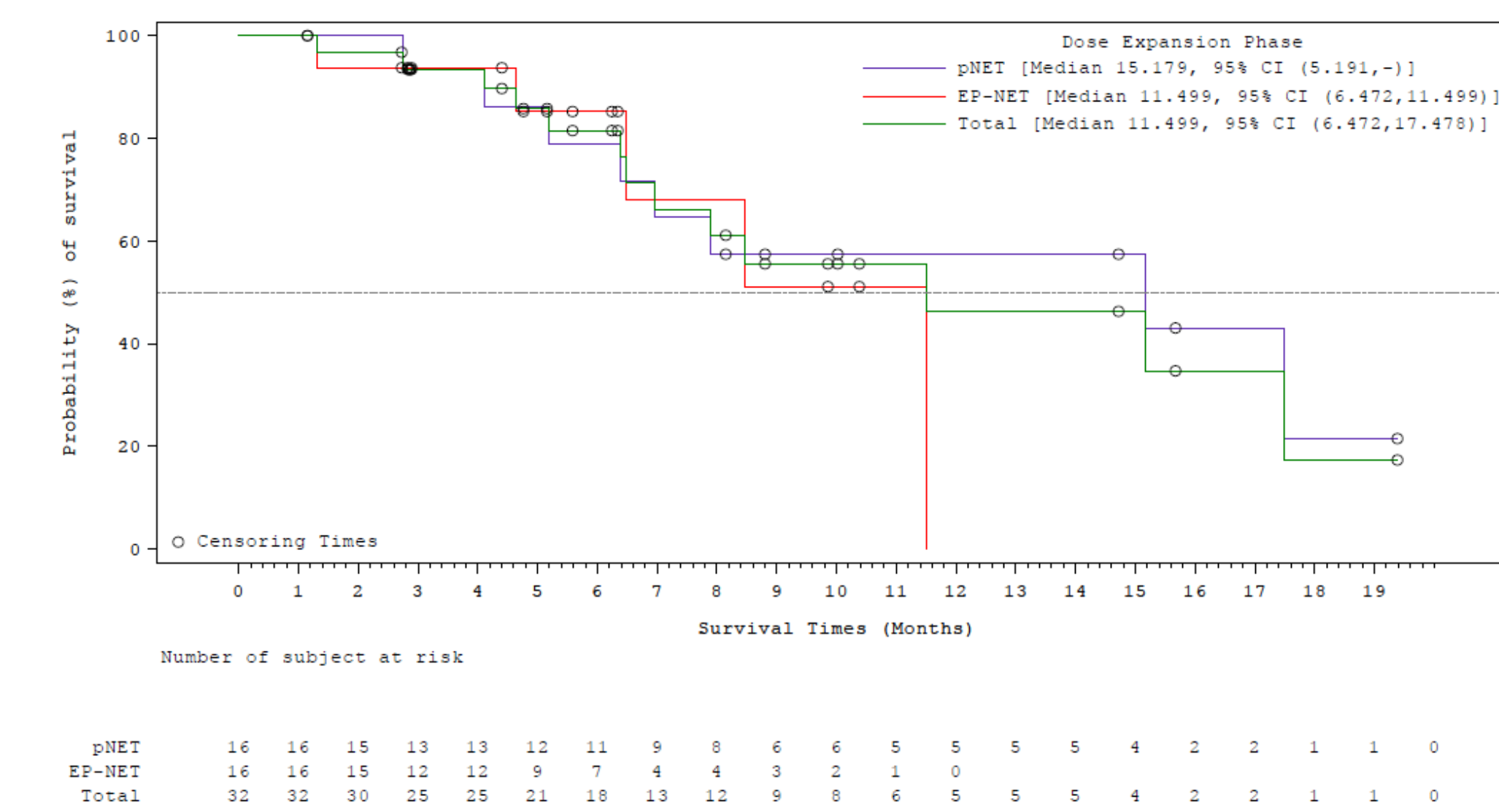
## SAFETY

- The safety profile of surufatinib remains consistent with previously completed trials
- All pts (n=32) had reported at least 1 adverse event (AE), and 24 pts (75%) reported AEs ≥ grade 3
- Serious Adverse Events occurred in 43.8% of pts
- AEs leading to treatment discontinuation occurred in 7 pts (21.9%)
- AEs leading to dose reduction occurred in 9 pts (28.1%)
- AEs leading to dose interruption occurred in 18 pts (56.3%)

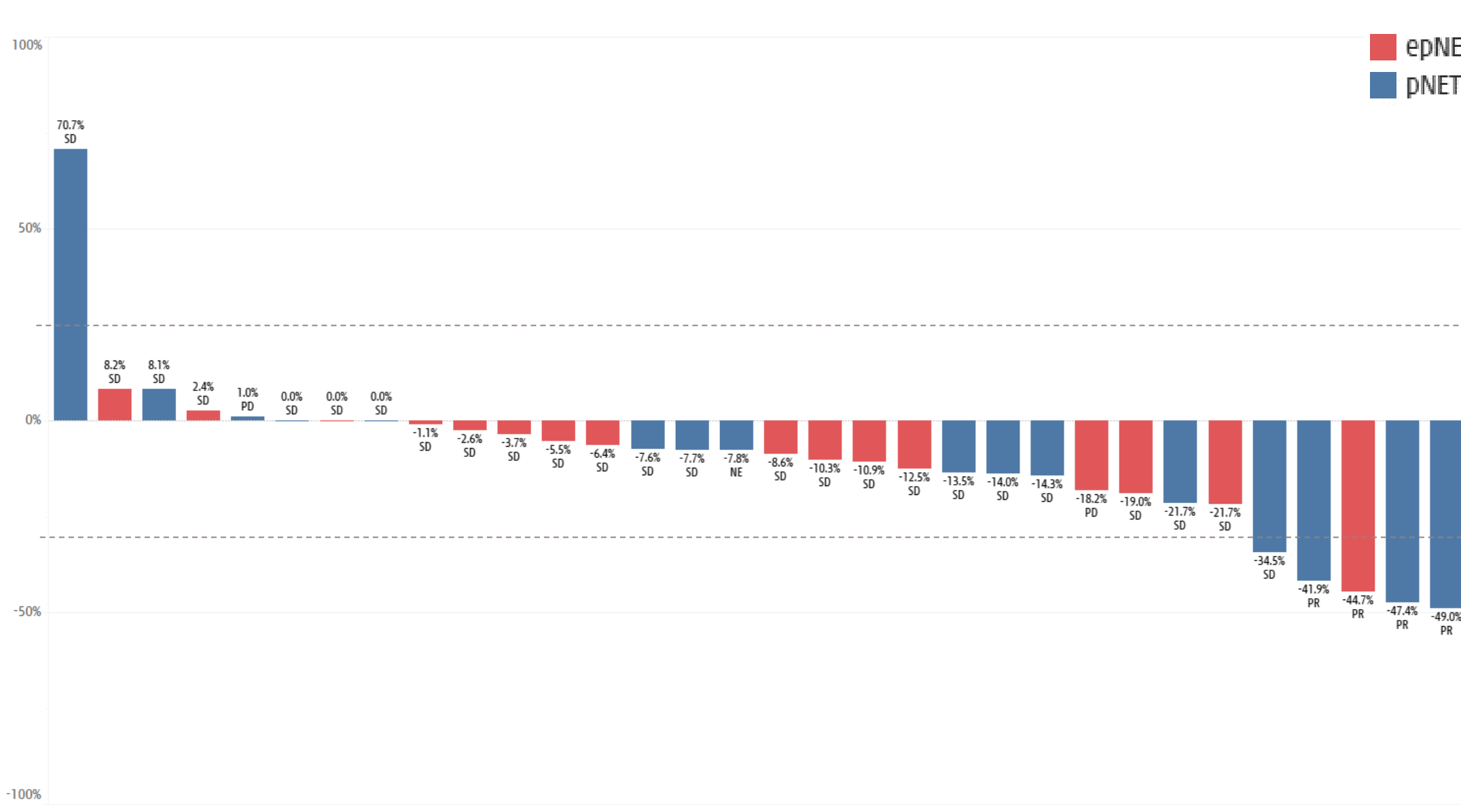
## EFFICACY

- 32 pts with heavily pretreated progressive NETs (16 epNET and pNET each) were enrolled in the Dose Expansion
- The median age was 62.2 years (44-75) and 64.4 years (39-72) for epNET and pNET pts, respectively
- 65.6% of pts received ≥3 prior lines of treatment
- Median lines of therapy: epNET: 2 [2-5]; pNET: 4 [1-8]
- All pts previously received everolimus and/or sunitinib
- As of the data cutoff of 30-Jun-20, 7 pts remained on treatment (4 epNET; 3 pNET)
- Median number of cycles received was 8 (range: 2,15) for epNET and 8.5 (range: 2,23) for pNET

## PROGRESSION FREE SURVIVAL



## BEST % CHANGE IN TARGET LESION DIAMETER



## BASELINE DEMOGRAPHICS

	pNET (N=16)	epNET (N=16)
Median age, years (minimum, maximum)	64.4 (39.0, 72.0)	62.2 (44.0, 75.0)
Age group, n (%)		
<65 years	9 (56.3)	9 (56.3)
≥65 years	7 (43.8)	7 (43.8)
Gender, n (%)		
Male	11 (68.8)	11 (68.8)
Female	5 (31.3)	5 (31.3)
Race, n (%)		
Asian	2 (12.5)	0
Black or African American	0	4 (25.0)
White	6 (37.5)	9 (56.3)
Other	0	3 (18.8)
Not Reported	8 (50.0)	0
Ethnicity, n (%)		
Hispanic or Latino	1 (6.3)	4 (25.0)
Not Hispanic or Latino	7 (43.8)	12 (75.0)
Baseline ECOG PS		
0	3 (18.8)	8 (50.0)
1	13 (81.3)	8 (50.0)

## ANTI-TUMOR ACTIVITY

	epNET (n=16)	pNET (n=16)	Total (n=32)
Confirmed best overall response, n (%)			
Complete response (CR)	0	0	0
Partial response (PR)	1 (6.3)	3 (18.8)	4 (12.5)
Stable disease (SD)	14 (87.5)	11 (68.8)	25 (78.1)
Progressive disease (PD)	1 (6.3)	1 (6.3)	2 (6.3)
Not evaluable (NE)	0	1 (6.3)	1 (3.1)
Objective response rate (ORR), n (%) (95% CI)	1 (6.3) (0.2, 30.2)	3 (18.8) (4.0, 45.6)	4 (12.5) (3.5, 29.0)
Disease control rate (DCR), n (%) (95% CI)	15 (93.8) (69.8, 99.8)	14 (87.5) (61.7, 98.4)	29 (90.6) (75.0, 98.0)
Progression free survival (PFS)			
Median, months (95% CI)	11.5 (6.47, 11.50)	15.2 (5.19, NR)	11.5 (6.47, 17.48)
PFS rate at 11 months % (95%CI)	51.1 (12.8, 80.3)	57.4 (28.7, 78.2)	55.6 (32.3, 73.7)

## SAFETY

Treatment-Emergent Adverse Events (TEAE) in >20% of Patients

SOC Preferred Term	epNET (N=16) n (%)		pNET (N=16) n (%)		Total (N=32) n (%)	
	Any Grade	≥ Grade 3	Any Grade	≥ Grade 3	Any Grade	≥ Grade 3
Any TEAE	16 (100.0)	13 (81.3)	16 (100.0)	11 (68.8)	32 (100)	24 (75.0)
Fatigue	11 (68.8)	1 (6.3)	4 (25.0)	0	15 (46.9)	1 (3.1)
Hypertension	7 (43.8)	6 (37.5)	7 (43.8)	6 (37.5)	14 (43.8)	12 (37.5)
Proteinuria	5 (31.3)	1 (6.3)	7 (43.8)	1 (6.3)	12 (37.5)	2 (6.3)
Diarrhea	6 (37.5)	2 (12.5)	5 (31.3)	1 (6.3)	11 (34.4)	3 (9.4)
Vomiting	5 (31.3)	0	4 (25.0)	1 (6.3)	9 (28.1)	1 (3.1)
Nausea	5 (31.3)	0	3 (18.8)	1 (6.3)	8 (25.0)	1 (3.1)
Oedema peripheral	2 (12.5)	1 (6.3)	5 (31.3)	0	7 (21.9)	1 (3.1)

## CONCLUSIONS

- Surufatinib has demonstrated anti-tumor activity in heavily pretreated US pts with progressive NETs with a manageable safety profile
- This is consistent with 2 completed phase 3 trials
- Surufatinib continues to be studied in other ongoing clinical trials globally
- A New Drug Application has been submitted to the US FDA for review.

### CONTACT EMAIL

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### ACKNOWLEDGMENT

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### REFERENCES

- Xu et al. *The Lancet Oncology*. 2020; 21: 1489-99.
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