

FID-007 in combination with cetuximab in recurrent or metastatic head and neck squamous cell carcinoma (FID-007-003)

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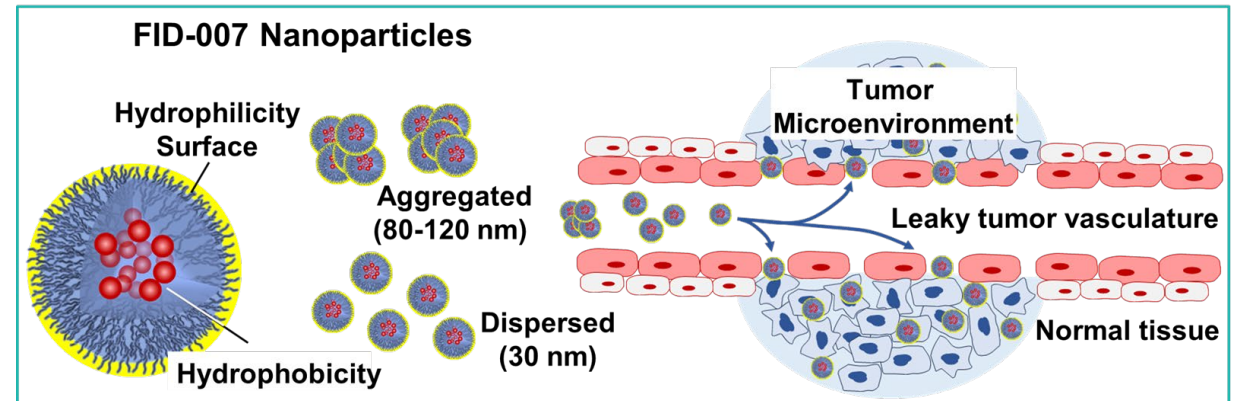
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Key Takeaway Points

- **FID-007 is a novel nanoencapsulated paclitaxel formulation**
- **FID-007 demonstrated encouraging clinical activity when combined with cetuximab in patients with R/M HNSCC**
 - **Efficacy**
 - ORR: 61.9%
 - mDOR: 7.4 mo (95% CI: 3.7-11.1)
 - mPFS (ITT): 6.7 mo (95% CI: 5.4-9.2)
 - mOS: not mature; 1-Year OS: 63.4%
 - **Safety**
 - Manageable safety profile with no infusion-related reaction or grade ≥ 3 peripheral neuropathy

Background of FID-007

- Nanoencapsulated paclitaxel formulation to promote tumor penetration and retention
- PK showed a rapid and more extensive distribution to tissue/tumor with lower exposures of unbound paclitaxel when compared to solvent-based paclitaxel
- Enhanced chemotherapy agent as backbone for combination therapy



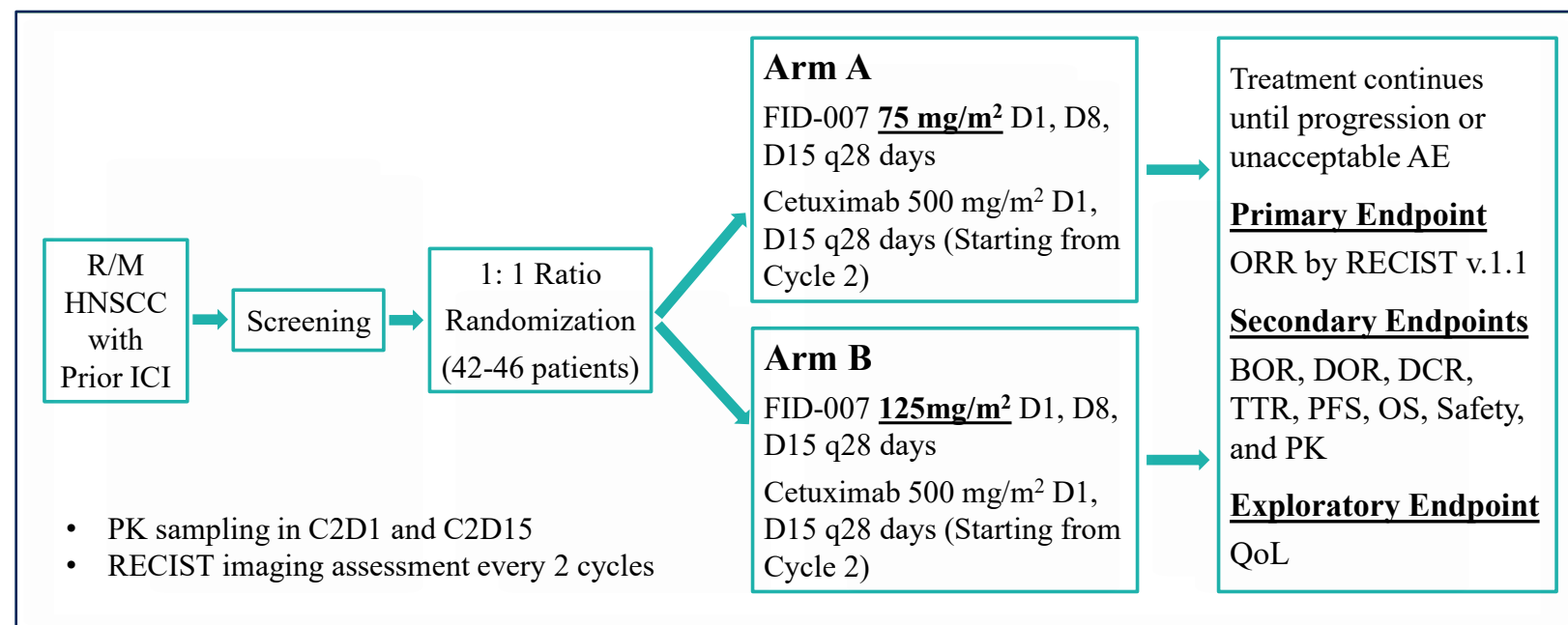
A first-in-human study of FID-007 monotherapy in advanced solid tumors (NCT03537690, N=50) demonstrated:

- a manageable safety profile without any grade ≥ 3 peripheral neuropathy
- an ORR of 45% in a subset of 11 heavily pre-treated patients with R/M HNSCC

Study Design

Key Eligibility Criteria

- R/M HNSCC
- Disease progression after ≤ 1 prior line of systemic therapy in the R/M setting
- ECOG PS of 0 or 1
- Patients must have prior ICI treatment
- Patients with prior cetuximab or taxane treatment in the R/M setting is excluded.



Clinical Cut-Off Date: April 16, 2026

Demographics and Baseline Disease Characteristics

		Arm A N=22 (%)	Arm B N=24 (%)
Age (years)	Median (min, max)	64.5 (49, 81)	66.0 (45, 79)
Gender	Male	17 (77.3)	20 (83.3)
	Female	5 (22.7)	4 (16.7)
Ethnicity	Hispanic or Latino	1 (4.5)	8 (33.3)
	Non-Hispanic or Latino	21 (95.5)	16 (66.7)
ECOG PS	0	4 (18.2)	10 (41.7)
	1	18 (81.8)	14 (58.3)
Primary Tumor Location	Oral cavity	12 (54.5)	13 (54.2)
	Oropharynx	8 (36.4)	8 (33.3)
	Larynx	2 (0.9)	2 (8.3)
	Paranasal sinuses	0	1 (4.2)
Prior ICI	Yes	22 (100)	24 (100)
Prior Platinum Tx	Yes	15 (68.2)	15 (62.5)
Prior Systemic Tx	Locally advanced (LA) only	8 (36.4)	7 (29.2)
	Recurrent / Metastatic (R/M) only	7 (31.8)	10 (41.7)
	Both LA and R/M	7 (31.8)	7 (29.2)
HPV (p16) Status	Positive, Oropharynx	7 (31.8)	6 (25.0)
	All other	15 (68.2)	18 (75.0)

Enrollment is completed as of Clinical Cut-Off Date April 16, 2026

- 46 patients were randomized and received ≥ 1 dose of FID-007 (ITT and safety populations)
- 42 patients were efficacy-evaluable

Platinum = carboplatin or cisplatin

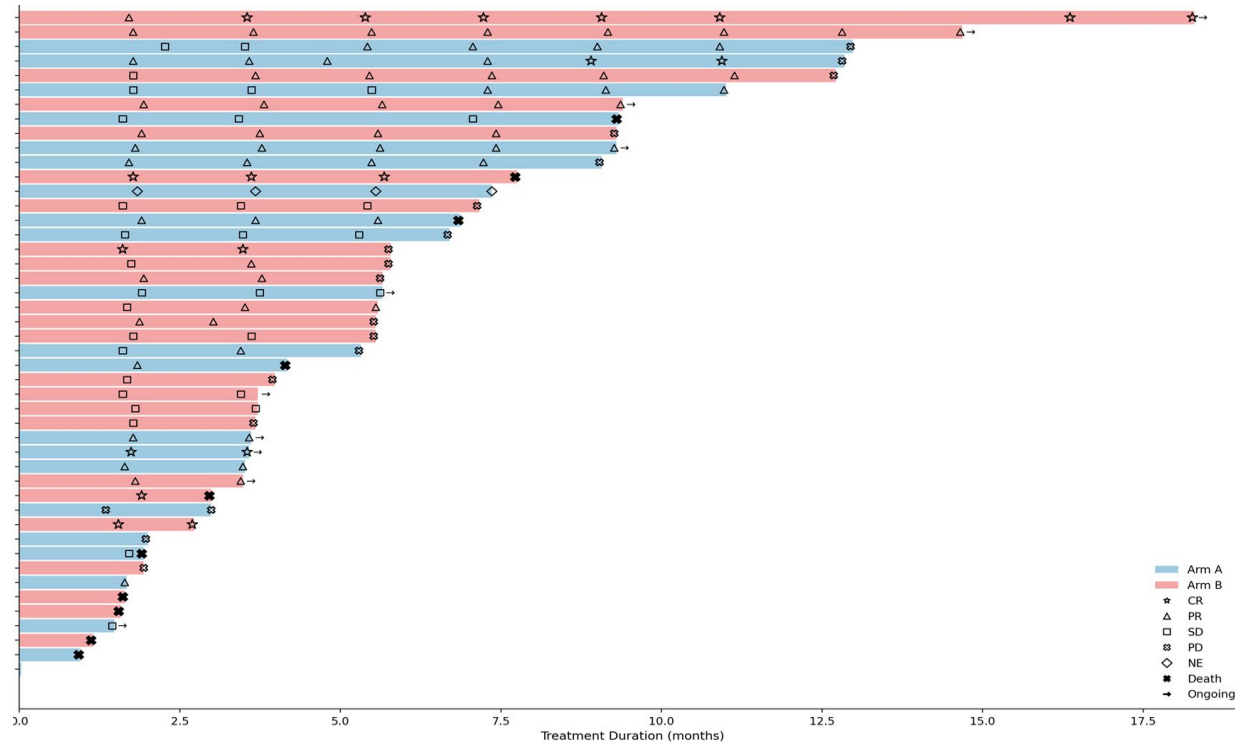
Best Overall Response

	Arm A (N=21)	Arm B (N=21)	Total (N=42)
BOR, n(%)			
CR	2 (9.5)	5 (23.8)	7 (16.7)
PR	10 (47.6)	9 (42.9)	19 (45.2)
SD	4 (19.0)	6 (28.6)	10 (23.8)
PD	3 (14.3)	1 (4.8)	4 (9.5)
NE	2 (9.5)	0	2 (4.8)
ORR, n (%)	12 (57.1)	14 (66.7)	26 (61.9)
DCR, n (%)	16 (76.2)	20 (95.2)	36 (85.7)

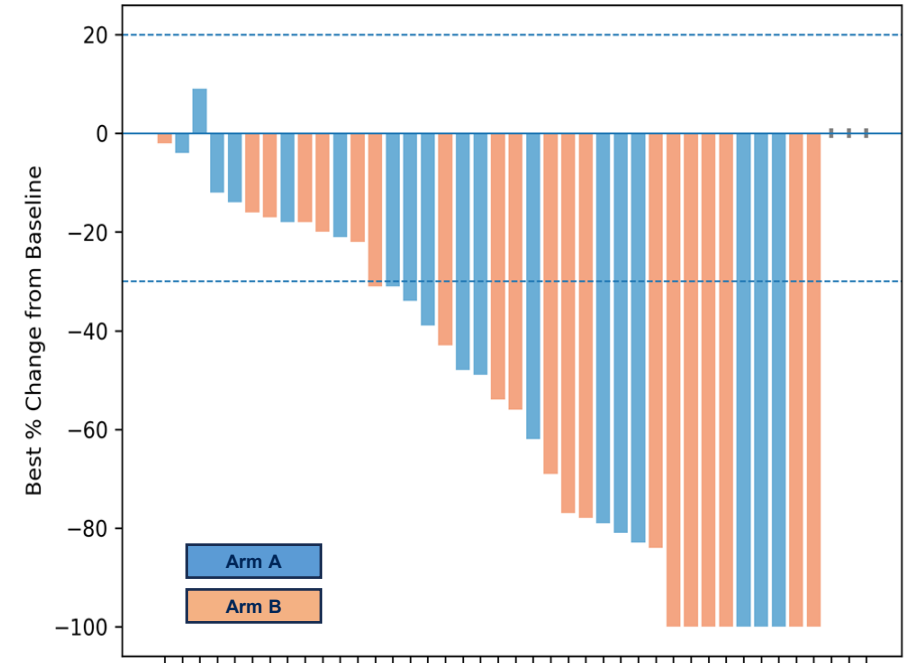
Subgroup	Category	ORR, n (%)
p16 status	p16 Positive OPC (N=11)	5 (45.5)
	Other HNSCC (N=31)	21 (67.7)
Prior Platinum Therapy	Yes (N=27)	17 (63.0)
	No (N=15)	9 (60.0)

Tumor Response and Treatment Duration

Duration of Response and Time to Response



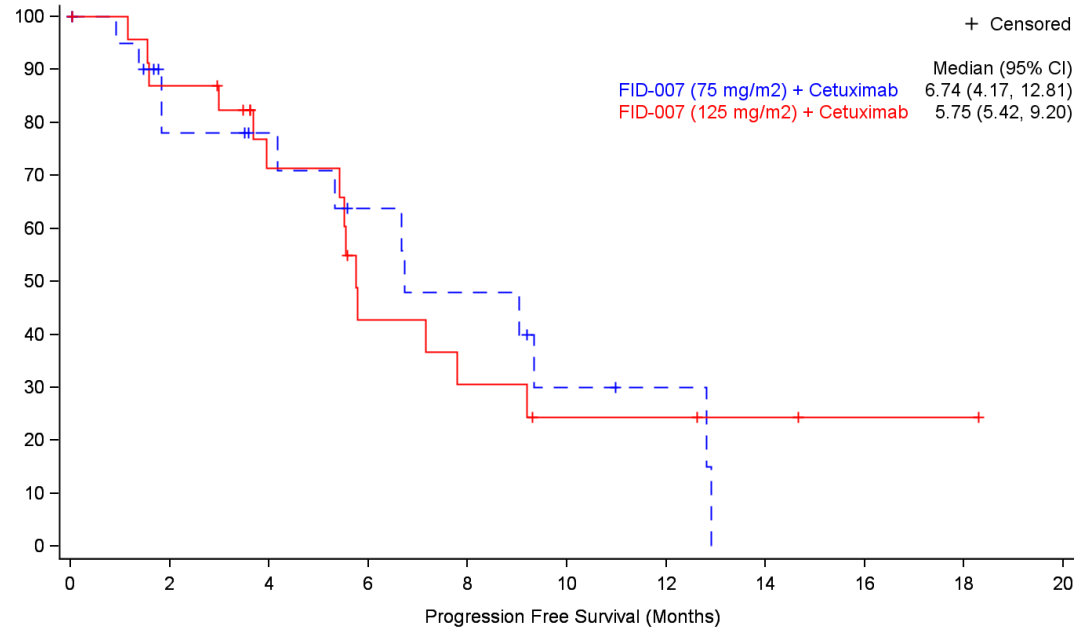
Best Overall Change in Tumor Size of Target Lesions from Baseline



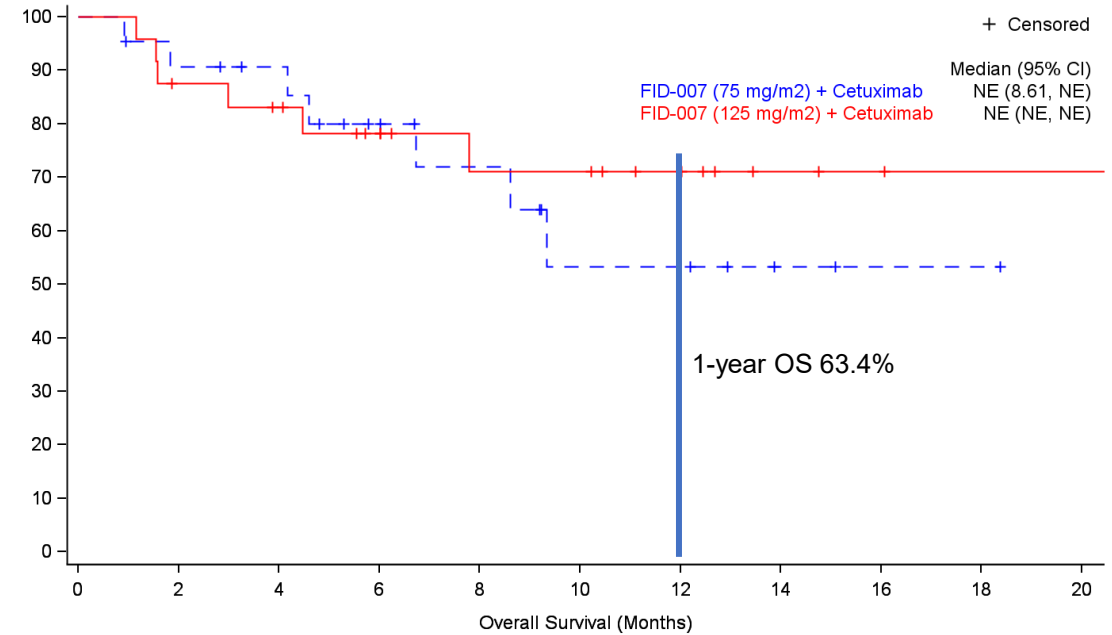
Responders	Arm A (N=12)	Arm B (N=14)
Median DOR (95% CI, mo)	7.36 (1.87, NE)	5.98 (2.17, NE)
Median TTR (Min, Max, mo)	1.77 (1.68, 7.29)	1.84 (1.64, 3.61)

Tumor Response and Treatment Duration

**Progression-Free Survival
(ITT Population)**

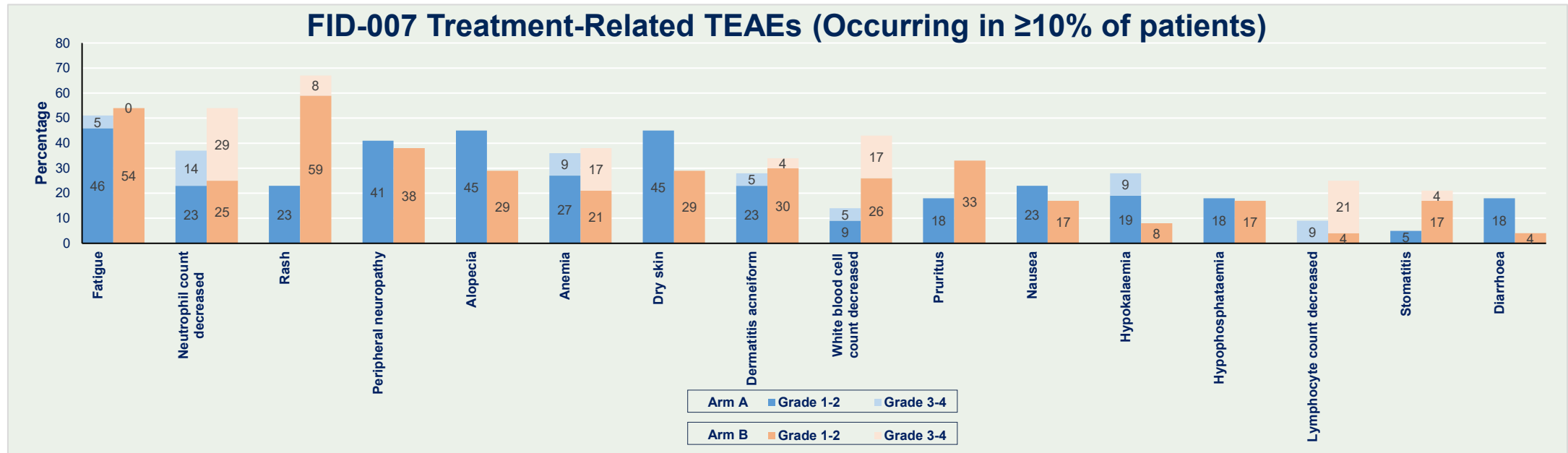


**Overall Survival
(ITT Population)**



ITT population	Arm A (N=22)	Arm B (N=24)	Total (N=46)
Median PFS (95% CI, mo)	6.74 (4.17, 12.81)	5.75 (5.42, 9.20)	6.67 (5.42, 9.20)

Summary of Adverse Events



Adverse event category, n (%)	Arm A (N=22)	Arm B (N=24)	Total (N=46)
Any TEAEs	20 (90.9)	24 (100)	44 (95.7)
Any TEAEs of >= CTCAE Grade 3	15 (68.2)	22 (91.7)	37 (80.4)
Any TEAEs related to FID-007	20 (90.9)	24 (100)	44 (95.7)
Any TEAEs related to Cetuximab	18 (81.8)	21 (87.5)	39 (84.8)
Any serious TEAEs	10 (45.5)	13 (54.2)	23 (50.0)
Any TRAEs leading to dose modification of FID-007	11 (50.0)	19 (79.2)	30 (65.2)
Any TRAEs leading to withdrawal of FID-007	0	2 (8.3)	2 (4.3)
Any TRAEs leading to death*	0	1 (4.2)	1 (2.2)

* 1 Grade 5 TRAE in Arm B (pneumonia)

Conclusions

- **FID-007 demonstrated encouraging clinical activity when combined with cetuximab in patients with R/M HNSCC**
 - **Efficacy**
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 - **Safety**
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- **Phase 3 study**
 - 125 mg/m² dose is proposed for Phase 3 study.

Acknowledgements

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