

A Randomized Phase 2 Study of FID-007 Plus Cetuximab in Patients with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

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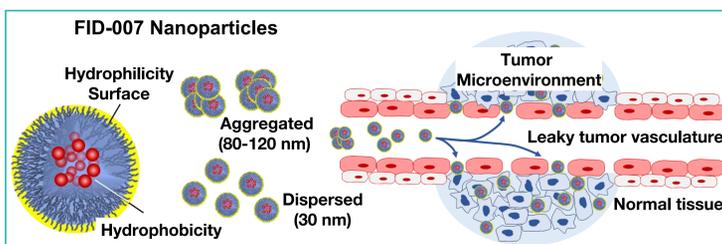
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BACKGROUND

Paclitaxel (PTX) is a microtubule targeting agent with activity across a wide range of solid tumors. However, the water-insoluble nature and the toxicities associated with its formulation remain significant challenges to optimizing its therapeutic potential.

FID-007 is designed to improve the pharmacokinetics of PTX, increase its water solubility, reduce formulation-related toxicity, and enhance therapeutic efficacy by encapsulating PTX with a clinically safe polyethyloxazoline (PEOX) polymer.

The smaller size of FID-007 nanoparticles (~30 nm) compared to solvent-based PTX micelles in plasma enables easy penetration and reduced clearance in tumor due to the enhanced permeability and retention effect¹, thereby leading to higher accumulation of FID-007 in the tumor tissue.

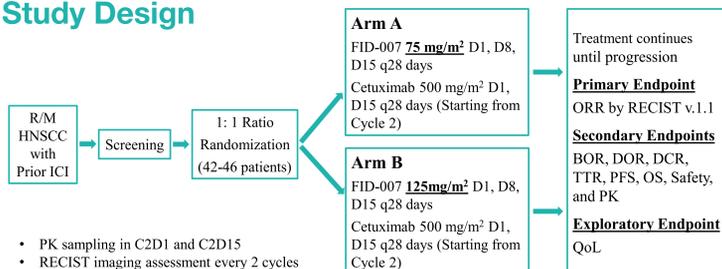


A first-in-human study of FID-007 monotherapy in advanced solid tumors (NCT03537690, N=50) demonstrated a tolerable safety profile without any Grade 3/4 peripheral neuropathy and an ORR of 45% in a subset of heavily pre-treated patients with recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC).

METHODS

FID-007-003 is a phase 2, randomized, multicenter, open-label study (NCT06332092), targeting to enroll 42-46 patients with disease progression after ≤1 prior line of systemic therapy for R/M HNSCC, including an immune checkpoint inhibitor (ICI).

Study Design



Eligibility Criteria

- R/M HNSCC of nasal/paranasal sinuses, nasopharynx (EBV-negative only), oral cavity, oropharynx, hypopharynx and larynx
- Disease progression after ≤1 prior line of systemic therapy (including an ICI) in the R/M setting
- ECOG PS of 0 or 1
- Patients with prior cetuximab or taxane treatment in the R/M setting is excluded.

* EEP includes all enrolled patients who received ≥1 dose of study treatment and either have ≥1 post-baseline radiological response assessment, or discontinued study due to clinical progression or death due to underlying disease before the 1st tumor assessment.

RESULTS

Enrollment

As of the data cut-off date of September 25, 2025, 39 patients have been randomized, 36 patients have received at least 1 dose of study treatment (FID-007 or cetuximab), and 35 patients are efficacy-evaluable (EEP)*.

Demographics and Baseline Characteristics

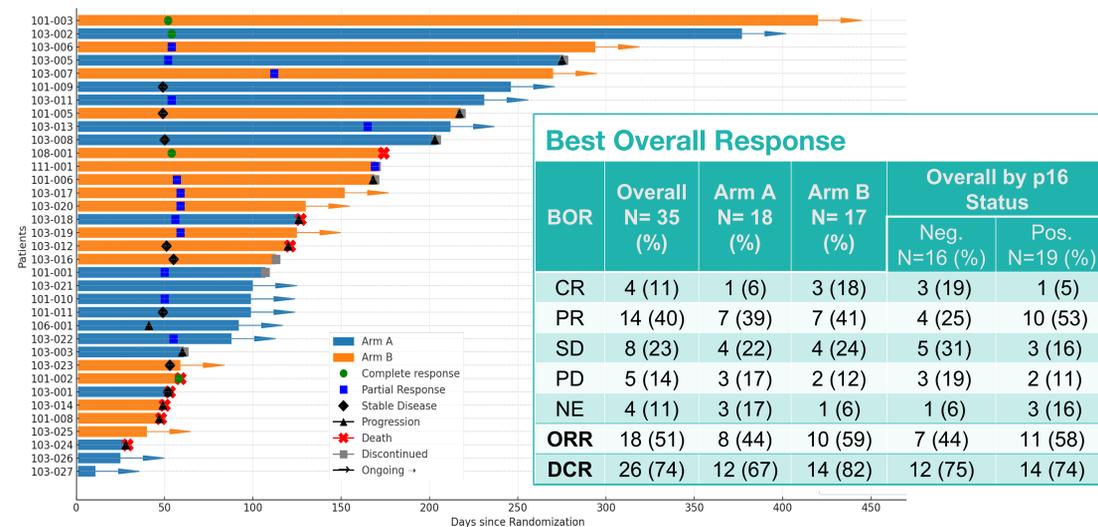
	Arm A N= 19 (%)	Arm B N=20 (%)
Age Group (years)		
Median	65	63
Range	49 - 81	45 - 78
Gender		
Male	14 (74)	16 (80)
Female	5 (26)	4 (20)
Race-Ethnicity		
Non-Hispanic White	16 (84)	12 (60)
Non-Hispanic Black	1 (5)	1 (5)
Hispanic (all races)	1 (5)	6 (30)
Other, non-Hispanic	1 (5)	0
HPV (p16) Status		
Negative	9 (47)	10 (50)
Positive	10 (53)	10 (50)

	Arm A N= 19 (%)	Arm B N=20 (%)
Prior Platinum Tx		
Yes	11 (58)	10 (50)
No	8 (42)	8 (40)
Not reported / Unknown	0	2 (10)
Prior ICI Tx		
Yes	19 (100)	18 (90)
No	0	0
Not reported / Unknown	0	2 (10)
Prior Taxane Tx		
Yes	0	1 (5)
No	19 (100)	17 (85)
Not reported / Unknown	0	2 (10)
Prior Systemic Tx		
Locally advanced only	4 (21)	3 (15)
Recurrent / Metastatic	15 (79)	16 (80)

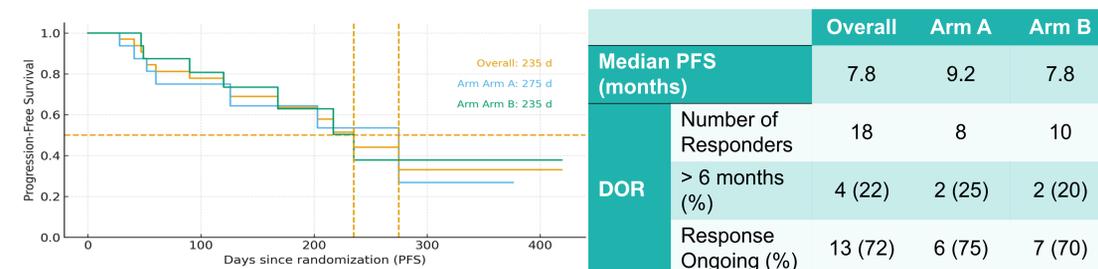
Platinum = carboplatin or cisplatin; ICI = pembrolizumab or nivolumab; Taxane = paclitaxel or docetaxel

Efficacy

Time to Response and Duration



Progression-Free Survival & Duration of Response



RESULTS

Safety

Overview of Treatment-Related Adverse Events

Number (%) of Patients	Overall N=36 (%)	Arm A N=19 (%)	Arm B N=17 (%)
Any serious TRAE	2 (6)	1 (5)	1 (6)
Any TRAE of Grade 3 or above	21 (58)	7 (37)	14 (82)
Any TRAE leading to death	1 (3)	1 (5)	0
Any TRAE leading to dose reduction	10 (28)	5 (25)	5 (29)
Any TRAE leading to treatment discontinuation	2 (6)	2 (11)	0

Treatment-Related Adverse Events (≥20% of Patients)

Preferred Term	Overall N=36 (%)		Arm A N=19 (%)		Arm B N=17 (%)	
	All Grades	Grade 3-5	All Grades	Grade 3-5	All Grades	Grade 3-5
Dry skin	24 (67)		14 (74)		10 (59)	
Rash maculo-papular*	20 (56)	2 (6)	6 (32)		14 (82)	2 (12)
Fatigue	19 (53)		9 (47)		10 (59)	
Neutrophil count decreased	16 (44)	6 (17)	6 (32)	2 (11)	10 (59)	4 (24)
Alopecia	14 (39)		7 (37)		7 (41)	
Hypomagnesaemia	14 (39)	2 (6)	7 (37)	1 (5)	7 (41)	1 (6)
Anaemia	13 (36)	3 (8)	6 (32)	1 (5)	7 (41)	2 (12)
Dermatitis acneiform	13 (36)	3 (8)	7 (37)	2 (11)	6 (35)	1 (6)
Peripheral sensory neuropathy**	11 (31)		4 (21)		7 (41)	
Pruritus	10 (28)		4 (21)		6 (35)	
Stomatitis	8 (22)	1 (3)	2 (11)		6 (35)	1 (6)
Lymphocyte count decreased	7 (19)	7 (19)	2 (11)	2 (11)	5 (29)	5 (29)
Pneumonia	1 (3)	1 (3)			1 (6)	1 (6)

* Included PTs Rash and Rash maculo-papular

** Includes PTs Peripheral sensory neuropathy and Neuropathy peripheral

CONCLUSIONS

- FID-007 combined with cetuximab demonstrated meaningful anticancer efficacy and favorable safety/tolerability profile at both dose levels for the ≤2nd line treatment of R/M HNSCC.
- An optimal dose of FID-007 will be determined after data maturation to support further development of this combination therapy.

References

- Matsumura Y, Maeda H. A new concept for macromolecular therapeutics in cancer chemotherapy: mechanism of tumor tropic accumulation of proteins and the antitumor agent smancs. Cancer Res. Dec 1986;46(12 Pt 1):6387-92.

Acknowledgements

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Disclosure

- Jacob Thomas has done consulting work for Merus.