BICARA THERAPEUTICS™

ASCO 2026

FICERA: enabling tumor penetration to drive deep and durable responses in HPV-neg HNSCC

May 22, 2026

Forward-looking statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements other than historical factual information are forward-looking statements, including without limitation express or implied statements regarding our strategy, business plans and focus; the clinical development of ficerafusp alfa, including the initiation, timing, progress, results and future data releases of our ongoing and planned clinical trials; the advancement of the FORTIFI-HN01 pivotal trial in 1L HPV-negative R/M HNSCC and our ongoing Phase 1/1b expansion cohorts; the initiation of an alternate dose study to evaluate a loading and every-three-week maintenance dosing regimen of ficerafusp alfa; the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy, depth, durability and tolerability as compared to the existing standard of care; the potential for U.S. regulatory approval and launch ficerafusp alfa; and the potential market opportunities for ficerafusp alfa and anticipated differentiators of ficerafusp alfa's clinical profile. In some cases, you can identify forward-looking statements because they contain words such as "may," "might," "will," "would," "shall," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "looks," "seeks," "predicts," "potential," "ongoing," or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions, although not all forward-looking statements are accompanied by such words. Forward-looking statements are based on assumptions and assessments made by our management in light of their experience and perceptions of historical trends, current conditions, expected future developments and other factors they believe to be appropriate, and speak only as of the date of this presentation.

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You should not rely upon forward-looking statements as predictions of future events or performance, or as a representation or warranty (express or implied) by us or any other person that we will achieve our objectives and plans in any specified time frame, on such specified terms, or at all. Although our management believes that the expectations reflected in our statements are reasonable, we cannot guarantee that the future results, performance or events and circumstances described in the forward-looking statements will be achieved or occur. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein.

Market data and industry information used throughout this presentation are based on management's knowledge of the industry and the good faith estimates of management. We also relied, to the extent available, upon management's review of independent industry surveys and publications and other publicly available information prepared by a number of third-party sources. All of the market data and industry information used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we believe that these sources are reliable as of their respective dates, we cannot guarantee the accuracy or completeness of this information, and we have not independently verified this information. Projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors. These and other factors could cause results to differ materially from those expressed in our estimates and beliefs and in the estimates prepared by independent parties.

This presentation discusses potential future product candidates that are investigational only and have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these potential future product candidates for the use for which such potential future product candidates are being studied.

Agenda & today's presenters

1

Ficerafusp alfa (FICERA) in 1L R/M HPV-Negative HNSCC

EGFR x TGF-β bifunctional antibody

Claire Mazumdar, Ph.D., MBA
Chief Executive Officer

2

ASCO 2026 Clinical Update

Extended Follow-up of **FICERA** + Pembrolizumab Across ~90 Patients in 1L R/M HPV-Negative HNSCC

Bill Schelman, M.D., Ph.D.
Chief Medical Officer

Joining for Q&A

Ryan Cohlhepp, Pharm.D.
President & Chief Operating Officer

Tanya Green
Chief Development Officer

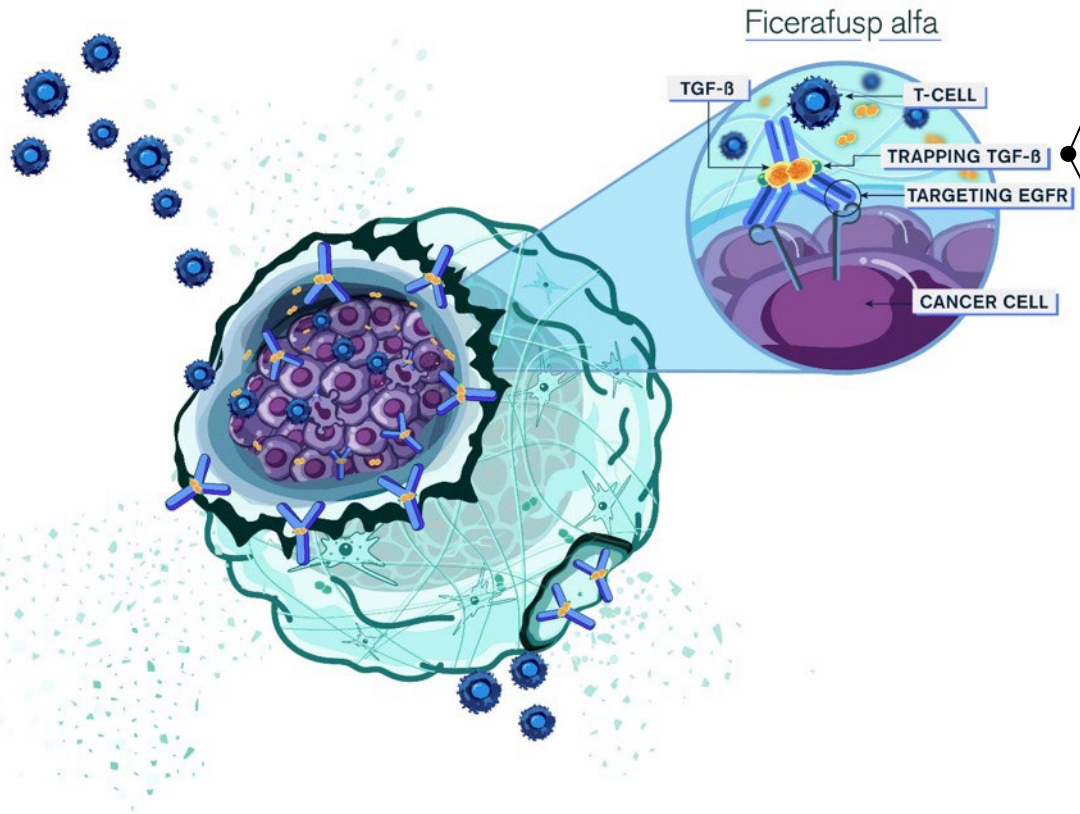
Ficerafusp Alfa (FICERA) in 1L R/M HPV-Negative HNSCC

EGFR x TGF-β bifunctional antibody

FICERA – EGFR-directed antibody combined with a TGF-β ligand trap designed to drive tumor penetration

Inadequate tumor penetration has challenged the treatment of many solid tumors including HPV-negative R/M HNSCC

FICERA was specifically designed to enable **tumor penetration** and drive **deep, durable responses** to yield **improved outcomes and survival**



1 **Targeting EGFR**

1. Direct anti-tumor effect
2. Drives tumor targeting

2 **Trapping TGF-β**

1. **Enables tumor penetration**
2. **Prevents resistance**

Boreddy SR, et al. Cancer Res. 2023;83(11): 1883-904.

Significant unmet need for better treatment options that improve outcomes in HPV-negative HNSCC patients

Head and neck cancer is a fast-growing global market with ~50K HPV-negative annually incident patients across major markets, including 18K in the U.S.#

Current standard of care

	Pembro[1]	Pembro + chemo[1]
ORR	~19%	~36%
Median DOR	~23.4 months	~6.7 months
Median PFS	~3.2 months	~5.0 months
Median OS		
HPV-all	~12.3 months	~13.6 months
HPV-negative	~9 months[2,3]	~7 months[2,3]

HPV-negative HNSCC…

- Represents the **vast majority (80 – 90%) of HNSCC** in the R/M setting
- Characterized by **high tumor burden** and **symptomatic disease**
- Has **worse prognosis** vs. HPV-positive HNSCC
- Testing for HPV status is **well-established in clinical guidelines** due to prognostic nature of HPV-association

1. Based upon historical data. Burtness, Barbara, et al. The Lancet 394.10212 (2019): 1915-1928. 2. Vasiliadou, Ifigenia, et al. International Journal of Cancer 155.5 (2024): 883-893. 3. Black, Christopher M., et al. Frontiers in Oncology 13 (2023): 1160144

Tessellon patient flow modeling; SEER; country specific registries; literature review. Evaluate Pharma 2025

ORR = Overall Response Rate; DOR = Duration of Response; PFS = Progression-Free Survival; OS = Overall Survival

Phase 1b expansion cohorts of FICERA + pembro in 1L R/M HPV-negative HNSCC

Part A: Dose escalation
(3+3 design)[1]

Ficerafusp alfa + pembrolizumab

R/M HNSCC

Ficerafusp alfa 240-1500mg QW IV
Pembrolizumab 200mg Q3W IV

Part B: Dose expansion in 1L R/M HPV-negative HNSCC
(Simon 2-stage design)[2-4]

Expansion cohorts

Ficerafusp alfa 750mg QW + Pembrolizumab 200mg Q3W (n=30)

Ficerafusp alfa 1500mg QW* + Pembrolizumab 200mg Q3W (n=28)

Ficerafusp alfa 2000mg Q2W + Pembrolizumab 400mg Q6W (n=27)

Primary objective:
Safety/tolerability

Secondary objectives:
PK/PD, immunogenicity, preliminary efficacy

Key inclusion criteria:
- 1L R/M HNSCC
- Primary tumor in oral cavity, oropharynx, larynx, or hypopharynx
- PD-L1 CPS ≥1†
- ECOG PS 0-1

1L, first-line; **CPS**, combined positive score; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **EE**, efficacy evaluable; **HNSCC**, head and neck squamous cell carcinoma; **HPV**, human papillomavirus; **IV**, intravenous; **MTD**, maximum tolerated dose; **PK/PD**, pharmacokinetics/pharmacodynamics; **Q2W**, every 2 weeks; **Q3W**, every 3 weeks; **Q6W**, every 6 weeks; **QW**, once weekly; **R/M**, recurrent or metastatic; **SA**, safety analysis.
*The 1500 mg QW cohort also enrolled HPV-positive patients, who were not included in the current analysis.; †PD-L1 CPS was assessed locally in archival or fresh samples using the 22C3 immunohistochemistry or other validated assay.
1. Hernando-Calvo A, et al. Clin Cancer Res. 2025;31(22):4623-32; 2. Hanna GJ, et al. J Clin Oncol. 2026;Epub May 8; 3. Kaczmar JM, et al. Ann Oncol. 2025;36(Suppl 4):S1958(667O); 4. Zandberg DP, et al. Int J Radiol Oncol Biol Phys. 2026;125(11):e26.
Median (95% CI) follow-up was: 750mg QW: 20 (20-22), 1500mg QW: 36 (36-43), 2000mg Q2W: 24 (12-27) months

ASCO 2026 key takeaways

1. At three years (median) of follow-up, FICERA + pembrolizumab demonstrated estimated OS of 31% – representing a ~2x increase vs. standard of care[1]

2. No new safety signals observed with up to three years of follow up, and FICERA continues to demonstrate a generally well-tolerated safety profile

3. TGF-β inhibition translates to unprecedented depth of response, driving clinically differentiated long-term outcomes including DOR, PFS, and OS

1. Based on a retrospective analysis of Supplementary Figure 1C, Vasiliadou, Ifigenia, et al. International Journal of Cancer 155.5 (2024): 883-893. No head-to-head studies have been conducted, and cross-trial comparisons differences in molecule composition, trial design, and patient population and characteristics..
DOR, duration of response. PFS, progression-free survival. OS, overall survival

ASCO 2026 Clinical Data Extended Follow-Up Across ~90 Patients in 1L R/M HPV-Negative HNSCC

Deep and Durable Responses | Long-Term Benefit | Manageable Safety

Baseline characteristics were balanced across cohorts and evaluated in patients across the spectrum of disease burden

	750mg QW (N=31)	1500mg QW (N=30)	2000mg Q2W (N=30)
Age, median (min-max)	64 (28-78)	63 (31-84)	63 (32-94)
Sex, n (%)			
Male	20 (65)	19 (63)	20 (67)
Female	11 (35)	11 (37)	10 (33)
Primary disease site, n (%)			
Oral cavity	19 (61)	14 (47)	19 (63)
Oropharynx (HPV-negative)	4 (13)	8 (27)	6 (20)
Hypopharynx	5 (16)	4 (13)	2 (7)
Larynx	3 (10)	4 (13)	3 (10)
CPS, n (%)			
1-19	12 (39)	15 (50)	15 (50)
≥20	19 (61)	15 (50)	15 (50)
LR vs DM disease, (%)			
LR only	16 (52)	9 (30)	19 (63)
DM only	5 (16)	7 (23)	5 (17)
LR + DM	10 (32)	14 (47)	6 (20)
Target lesion diameter (mm) at baseline, median (min-max)	41 (11-131)	49 (10-133)	33 (10-187)
Sum of target lesion diameters at baseline, n (%)			
>50 mm	10 (32)	14 (47)	11 (37)
>70 mm	4 (13)	8 (27)	7 (23)
ECOG PS, n (%)			
0	11 (35)	11 (37)	10 (33)
1	20 (65)	19 (63)	20 (67)

CPS, combined positive score; **DM**, distant metastatic; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **HPV**, human papillomavirus; **LR**, locoregional; **max**, maximum; **min**, minimum; **Q2W**, every 2 weeks; **QW**, once weekly.

Data snapshot: March 31, 2026

FICERA continued to exhibit a generally well-tolerated safety profile

Most frequently reported (≥20%) TEAEs related to ficerafusp alfa

Preferred term	750mg QW (N=31)		1500mg QW (N=30)		2000mg Q2W (N=30)	
	Any Grade*	Grade 3	Any Grade†	Grade 3	Any Grade*	Grade 3
Any TRAE	31 (100)	11 (35)	28 (93)	15 (50)	29 (97)	16 (53)
Dermatitis acneiform	27 (87)	1 (3)	23 (77)	4 (13)	24 (80)	3 (10)
Pruritus	13 (42)	1 (3)	16 (53)	1 (3)	11 (37)	1 (3)
Anemia	8 (26)	3 (10)	13 (43)	7 (23)	15 (50)	8 (27)
Hypomagnesemia	7 (23)	0	13 (43)	0	6 (20)	0
Fatigue	13 (42)	0 (0)	11 (37)	1 (3)	12 (40)	1 (3)
Dry skin	10 (32)	0	9 (30)	0	9 (30)	0
Hypophosphatemia	10 (32)	0	8 (27)	0	6 (20)	0
Hypokalemia	8 (26)	1 (3)	8 (27)	0	5 (17)	0
Stomatitis	13 (42)	4 (13)	8 (27)	0	11 (37)	3 (10)
Nausea	5 (16)	0	6 (20)	0	9 (30)	1 (3)
Epistaxis	11 (35)	1 (3)	5 (17)	0	12 (40)	0
Skin fissures	10 (32)	0	6 (20)	0	7 (23)	0
Headache	6 (19)	0	4 (13)	1 (3)	10 (33)	0
Infusion related reaction	6 (19)	1 (3)	4 (13)	1 (3)	7 (23)	0
Lipase increased	7 (23)	1 (3)	6 (20)	1 (3)	2 (7)	1 (3)
Amylase increased	8 (26)	1 (3)	4 (13)	0	1 (3)	0
Mouth bleeding	8 (26)	1 (3)	0	0	4 (13)	0

FICERA + pembrolizumab safety profile:

- The combination was generally well-tolerated with no new safety signals
- No treatment-related deaths were reported
- Low discontinuation rates due to TRAEs across dose levels: 750mg (6%), 1500mg (10%), 2000mg (7%)

*1 patient had grade 4 hypokalemia. †1 patient had grade 4 pericarditis.

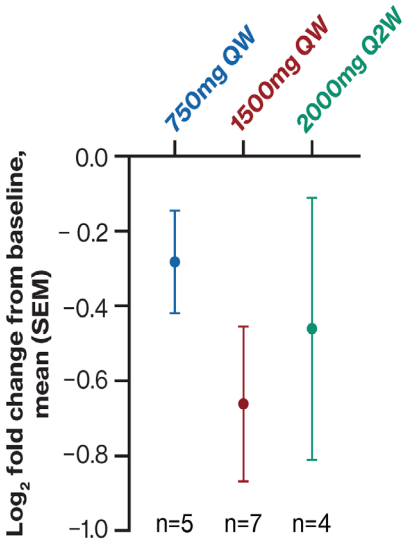
AE, adverse event; **EGFR**, epidermal growth factor receptor; **Q2W**, every 2 weeks; **QW**, once weekly; **TEAE**, treatment-emergent adverse event; **TGF-β**, transforming growth factor beta; **TRAE**, treatment-related adverse event.

Data snapshot: March 31, 2026

FICERA's TGF-β inhibition and tumor penetration are associated with deeper responses

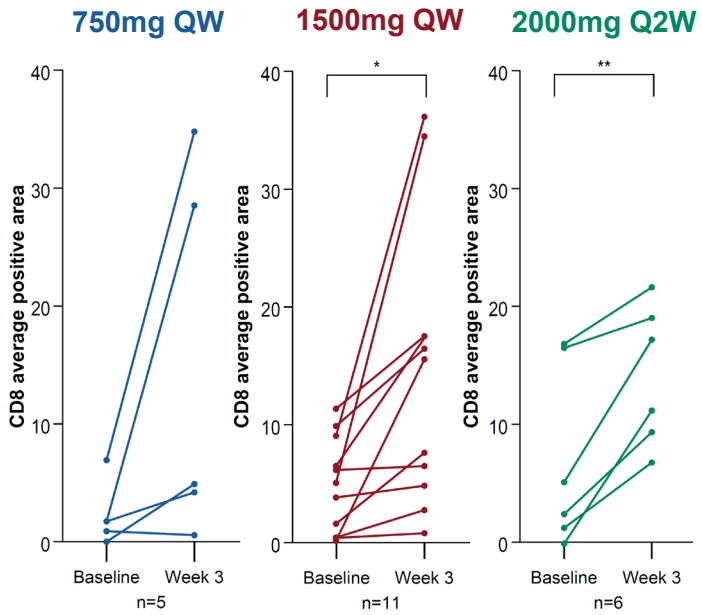
TGF-β Inhibition

pSMAD2 ⬇



Tumor Penetration

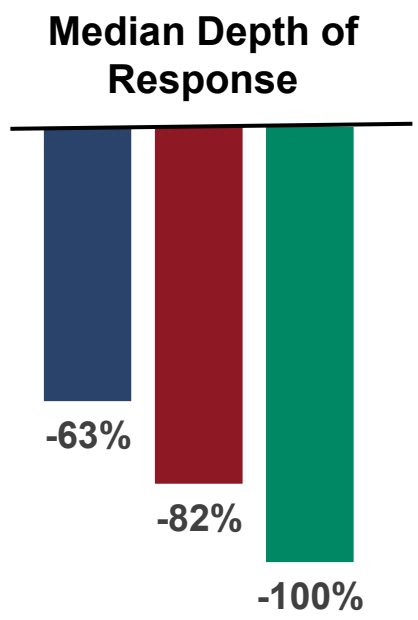
CD8+ T Cell Tumor Infiltration

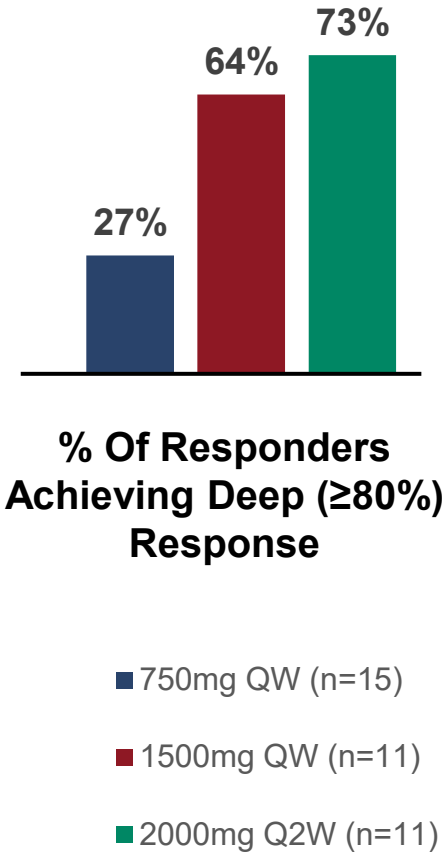


Plots show mean with SEM. Mann-Whitney Test from Log2 Baseline adjusted *p≤.05, **p ≤.01

Increases in TGF-β inhibition directly in the TME enabled greater tumor penetration to **drive deeper and more durable responses**

Depth of Response At 24-Weeks

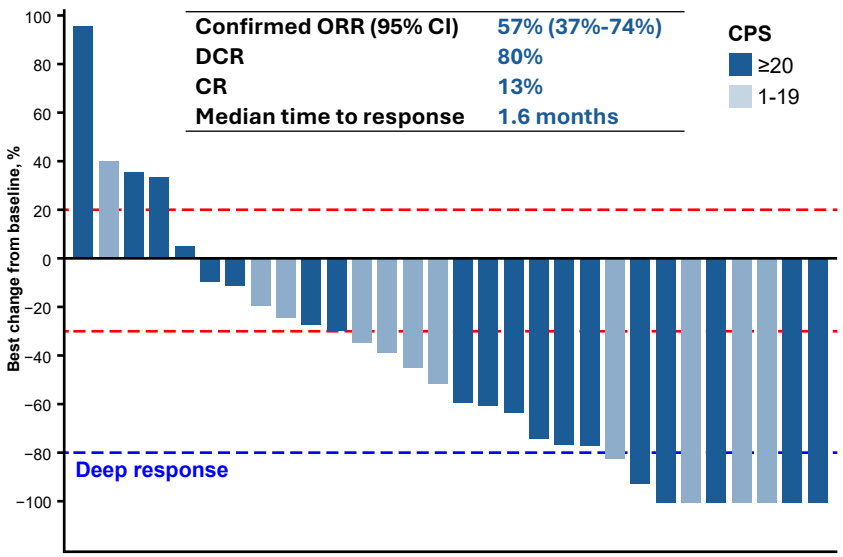




Bicara Therapeutics data on file. Paired tumor biopsies were analyzed by immunohistochemistry for pSMAD2. Cytokine analysis was performed on pre- and post-treatment (QW: 3 weeks, Q2W: 6 weeks) plasma samples using the Meso Scale Discovery platform. *p≤.05, **p ≤.01 (Mann-Whitney test).pSMAD2, phosphorylated SMAD2; Q2W, every 2 weeks; QW, once weekly; TGF-β, transforming growth factor beta; TNF-α, tumor necrosis factor alpha. Median depth of response represents the median of the best percent change from baseline amongst the confirmed responders at 24-weeks follow-up.

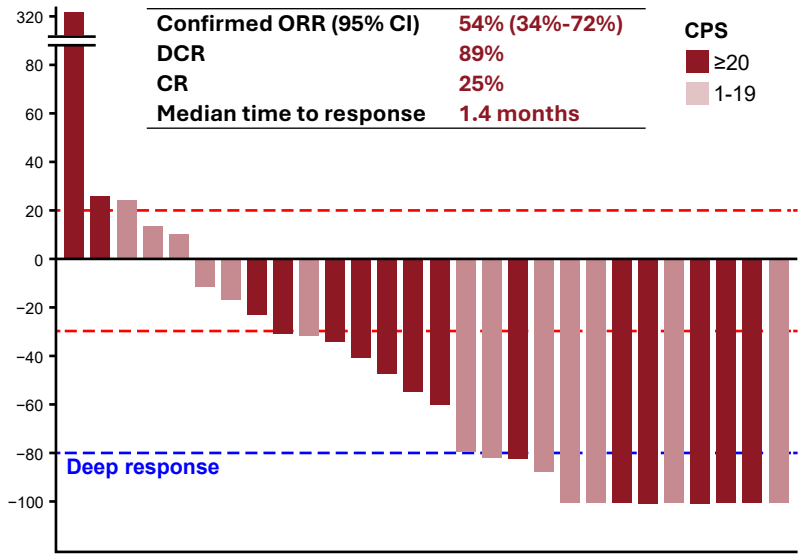
TGF-β inhibition drives rapid, deep responses and dose-dependent CR rates across cohorts

750mg QW



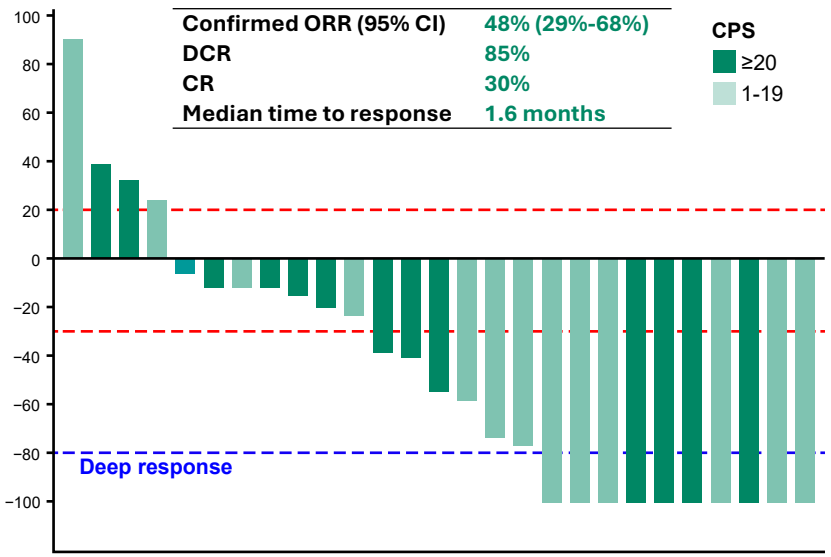
Deep response: 47% (8/17)

1500mg QW



Deep response: 80% (12/15)

2000mg Q2W



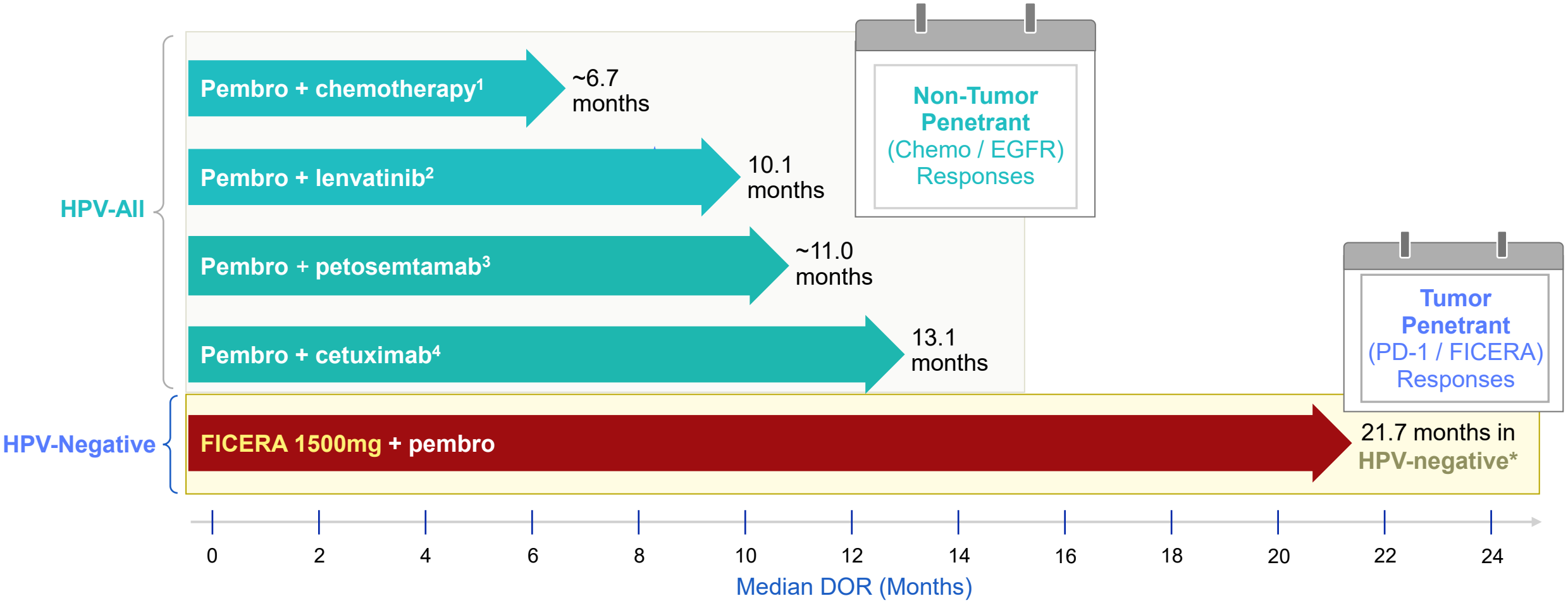
Deep response: 77% (10/13)

Data snapshot: March 31, 2026

Waterfall plots show best overall response (sum of target lesion diameters at baseline) for each patient.
CR, complete response; **CPS**, combined positive score; **DCR**, disease control rate; **ORR**, objective response rate; **Q2W**, every 2 weeks; **QW**, once weekly.

FICERA's tumor penetration was designed to drive durability

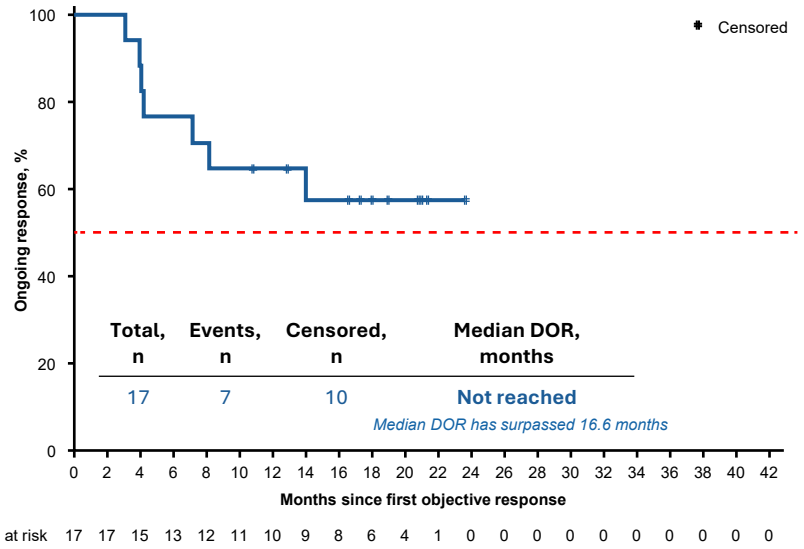
Median Duration of Response: Pembro Combinations in 1L R/M HNSCC



Based on historical published data. No head-to-head studies have been conducted, and cross-trial comparisons may not be reliable due to differences in molecule composition, trial design, and patient population and characteristics. Sources: 1. KEYNOTE-048: Burtness, Barbara, et al. The Lancet 394.10212 (2019). 2. LEAP-010: Licitra et al. MHNCS 2024,18(5) Abs 1. 3. Van Herpen, Carla ML, et al. J Clin Oncol 43, 6024(2025). 4. Sacco, et al. The Lancet Oncology 22.6 (2021): 883-892
*Data snapshot: March 31, 2026

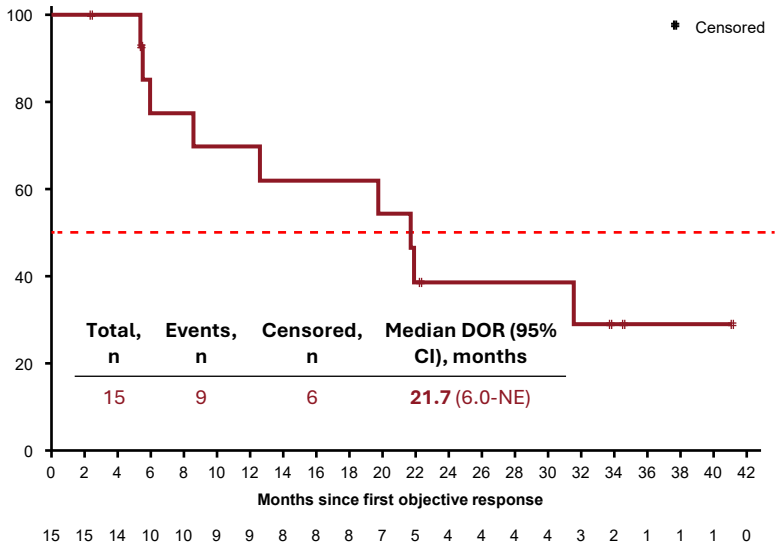
FICERA demonstrated clinically meaningful DOR across dose cohorts

750mg QW



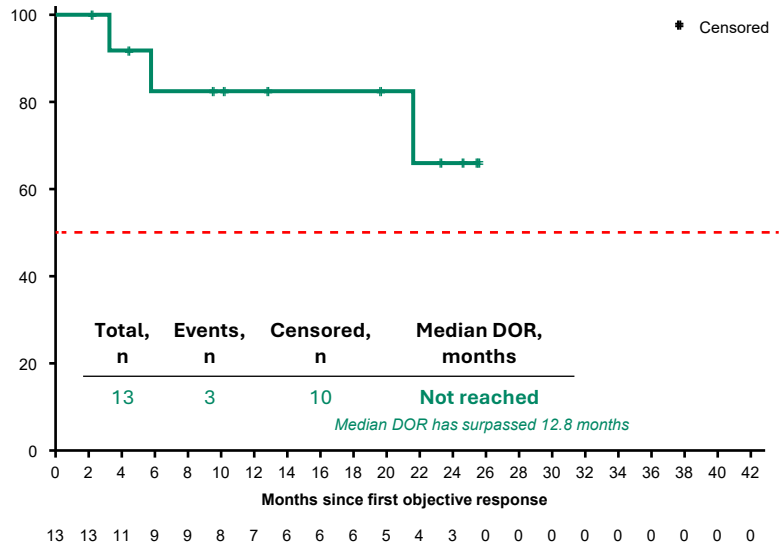
Median DOR: not yet reached; has surpassed 16.6 months

1500mg QW



Median DOR: 21.7 months

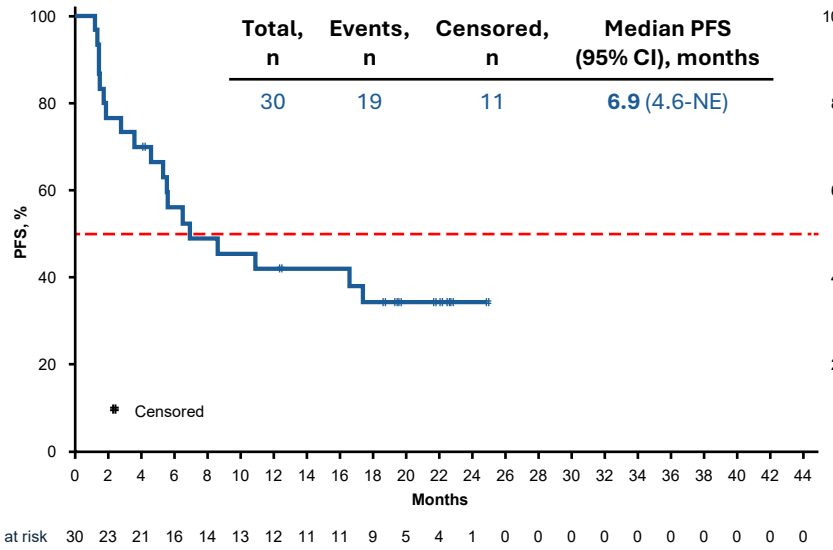
2000mg Q2W



Median DOR: not yet reached; has surpassed 12.8 months

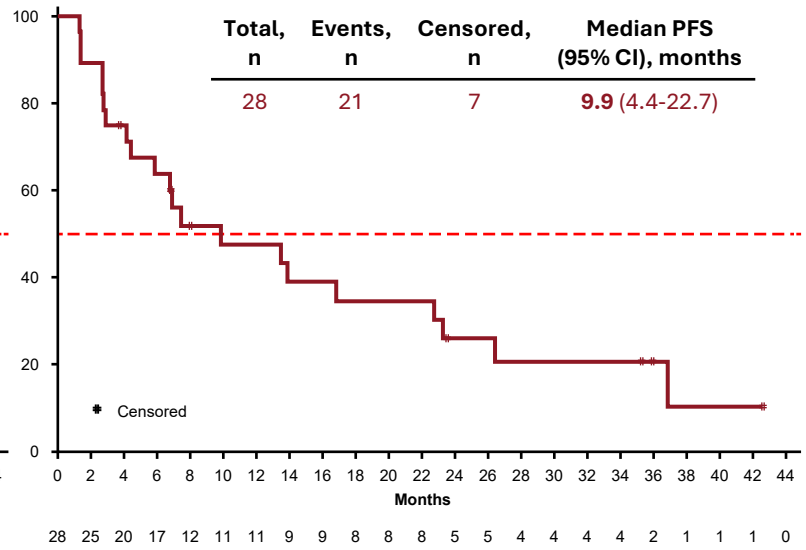
FICERA demonstrated clinically meaningful PFS across dose cohorts

750mg QW



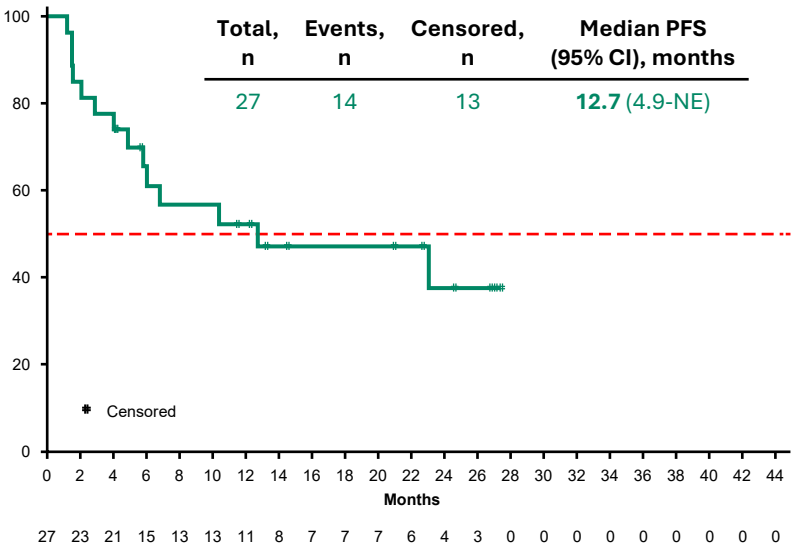
Median PFS: 6.9 months

1500mg QW



Median PFS: 9.9 months

2000mg Q2W



Median PFS: 12.7 months

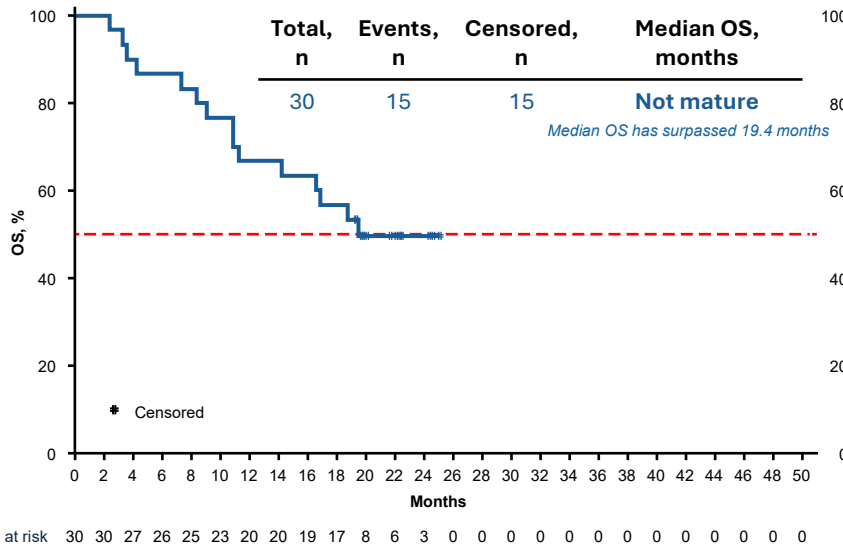
FICERA's median PFS of 9.9 months represents a **>3x increase** vs. pembrolizumab (~3.2 months[1])

1. Includes both HPV-positive and HPV-negative R/M HNSCC patients. Based on historical published data. No head-to-head studies have been conducted, and cross-trial comparisons may not be reliable due to differences in molecule composition, trial design, and patient population and characteristics. Vasiliadou, Ifigenia, et al. International Journal of Cancer 155.5 (2024): 883-893

PFS, progression-free survival; **Q2W**, every 2 weeks; **QW**, once weekly

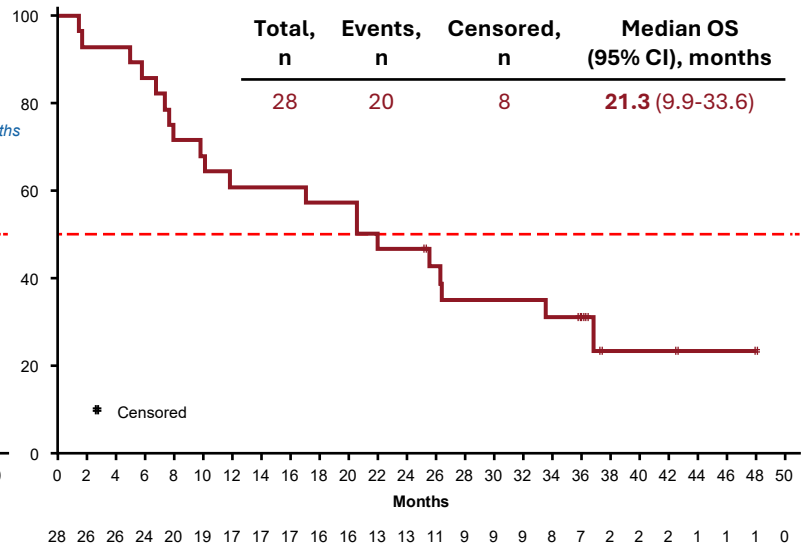
FICERA demonstrated clinically meaningful OS across dose cohorts

750mg QW



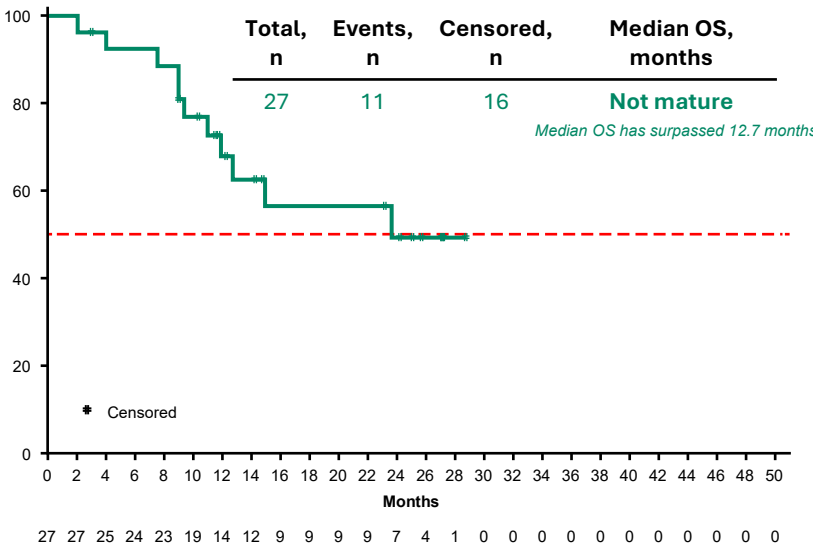
Median OS: not yet mature; has surpassed 19.4 months

1500mg QW



Median OS: 21.3 months

2000mg Q2W



Median OS: not yet mature; has surpassed 12.7 months; >23.6 months in patients with ≥2-year follow-up)[2]

At three years (median) FICERA delivered an estimated 31% OS, representing a **~2x increase vs. standard of care**[1]

1. Based on a retrospective analysis of Supplementary Figure 1C, Vasiliadou, Ifigenia, et al. International Journal of Cancer 155.5 (2024): 883-893. No head-to-head studies have been conducted, and cross-trial comparisons differences in molecule composition, trial design, and patient population and characteristics.
2. Data maturation reflects a bimodal enrollment distribution: in the initial 15 efficacy evaluable patients (median follow-up: 27 months) median OS is not mature but has surpassed 23.6 months. The remaining 12 efficacy evaluable patients had a median follow-up of 11.7 months.

OS, overall survival; **Q2W**, every 2 weeks; **QW**, once weekly.

FICERA demonstrated rapid, deep responses across disease burden, supporting a chemo-free therapeutic approach

Confirmed ORR by CPS score, tumor burden and disease site		750mg QW (n=30)	1500mg QW (n=28)	2000mg Q2W (n=27)
CPS, % (n/N)	1-19	**73** (8/11)	**54** (7/13)	**57** (8/14)
	≥20	**47** (9/19)	**53** (8/15)	**38** (5/13)
Tumor burden, % (n/N) (sum of target lesion diameters)	≤50 mm	**55** (11/20)	**53 (8/15)**	**53** (9/17)
	>50 mm	**60** (6/10)	**54** (7/13)	**40** (4/10)
	>70 mm	**50** (2/4)	**43** (3/7)	**33** (2/6)
Extent of disease, % (n/N)	LR only	**38** (6/16)	**62** (5/8)	**50** (7/14)
	DM only	**100** (5/5)	**29** (2/7)	**40** (2/5)
	LR + DM	**67** (6/9)	**62** (8/13)	**50** (4/8)

CPS 1-19:

FICERA delivered 54-73% ORR, more than 3x pembrolizumab monotherapy (~15%)[1]

1. Includes both HPV-positive and HPV-negative R/M HNSCC patients (CPS ≥ 1). Based on historical published data. No head-to-head studies have been conducted, and cross-trial comparisons may not be reliable due to differences in molecule composition, trial design, and patient population and characteristics. European Medicines Agency (CHMP); Keytruda Assessment Report, Procedure No. EMEA/H/C/003820/II/0065 (2019)

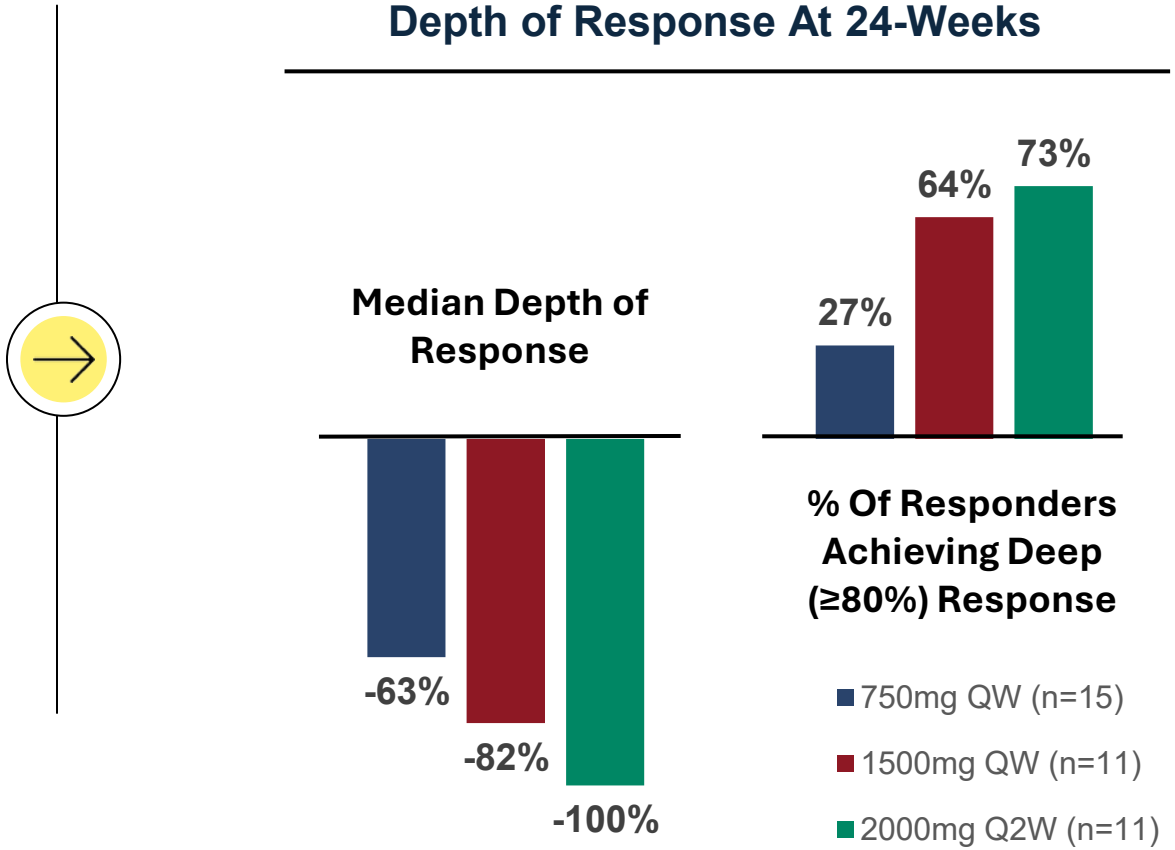
CPS, combined positive score; **DM**, distant metastatic; **LR**, locoregional; **ORR**, objective response rate; **Q2W**, every 2 weeks; **QW**, once weekly.

Pooled cohort analysis: depth of response is a predictor of long-term outcomes

Ficerafusp alfa 750mg QW + Pembrolizumab 200mg Q3W (n=30)

Ficerafusp alfa 1500mg QW + Pembrolizumab 200mg Q3W (n=28)

Ficerafusp alfa 2000mg Q2W + Pembrolizumab 400mg Q6W (n=27)

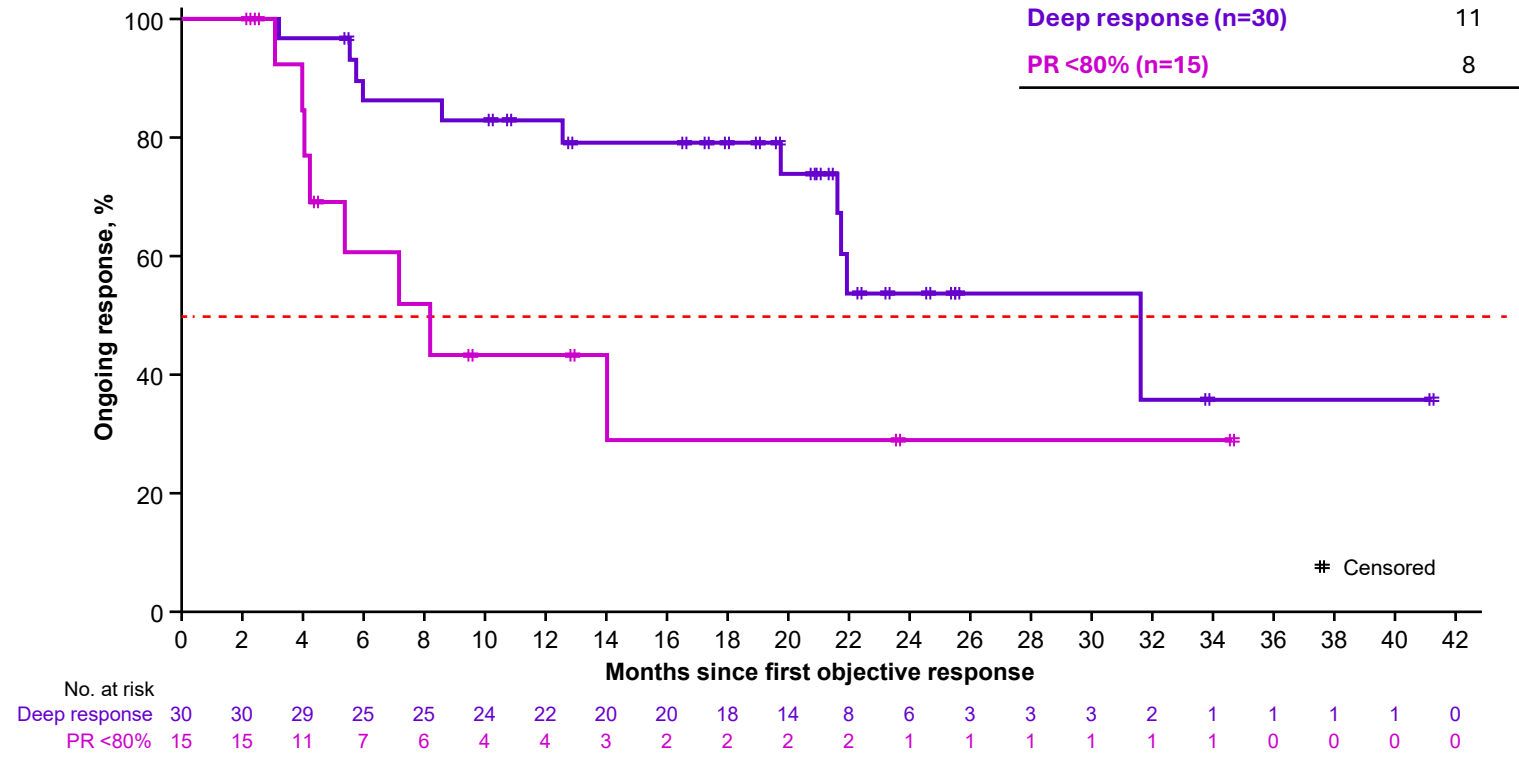


Median (95% CI) follow-up was: 750mg QW: 20 (20-22), 1500mg QW: 36 (36-43), 2000mg Q2W: 24 (12-27) months

Data snapshot: March 31, 2026

DOR: deep responders with ≥ 80% tumor shrinkage maintained DOR for a median 31.6 months across pooled cohort analysis

Depth of response	Events, n	Censored, n	Median DOR (95% CI), months
Deep response (n=30)	11	19	**31.6** (21.6-NE)
PR <80% (n=15)	8	7	**8.2** (4.0-NE)
			HR, 0.31 (95% CI, 0.11-0.84)

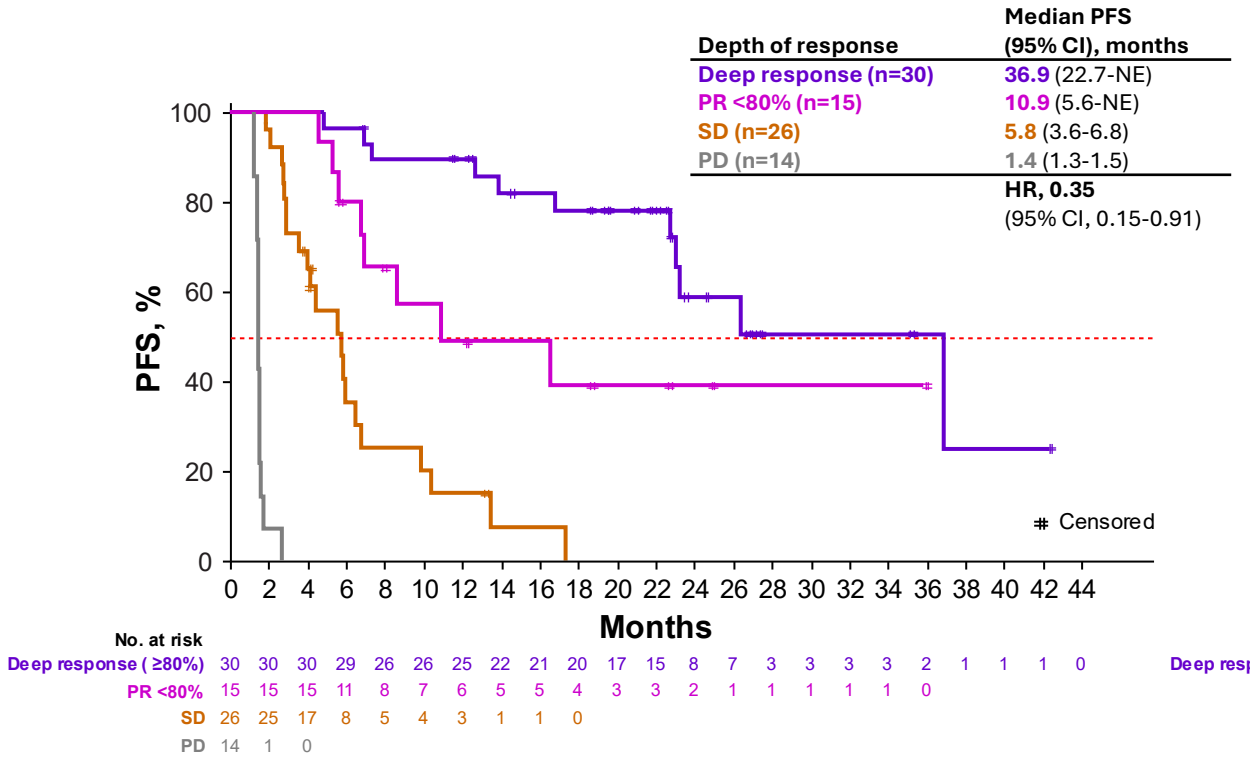


N=45 across 750mg, 1500mg, 2000mg dose cohorts

CI, confidence interval**; DOR**, duration of response; **HR**, hazard ratio; **NE**, not estimable; **OS**, overall survival; **PR**, partial response.

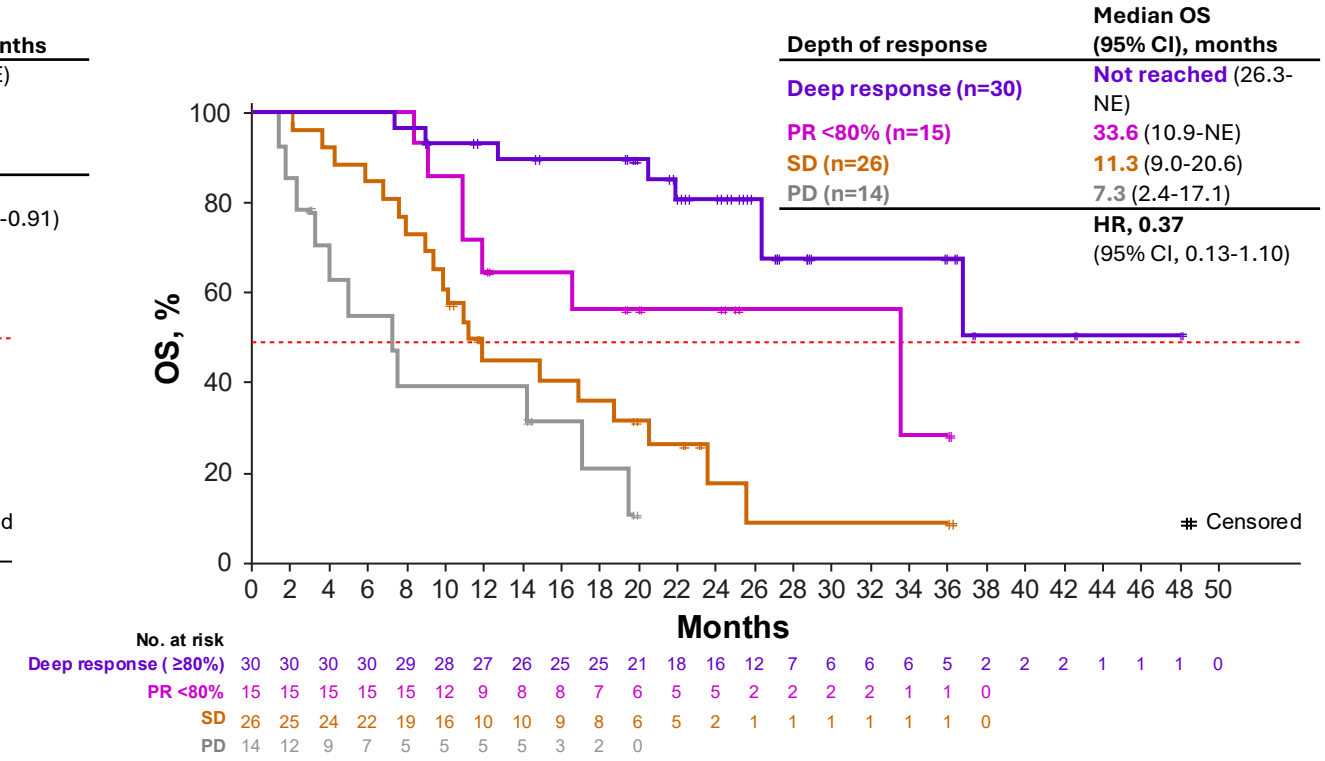
Data snapshot: March 31, 2026

PFS and OS: Deep responders showed durable and clinically meaningful benefit across pooled cohort analysis



PFS

Deep responders: 65% reduction in the risk of disease progression or death compared with PR <80%



OS

Deep responders: 63% reduction in the risk of death compared with PR <80%

CI, confidence interval; DOR, duration of response; **HR**, hazard ratio; **NE**, not estimable; **PFS,** progression-free survival; **OS**, overall survival; **PR**, partial response.

N=45 across 750mg, 1500mg, 2000mg dose cohorts

Data snapshot: March 31, 2026

FICERA's clinical profile aligns with what oncologists say matters most at the point of treatment selection

More impact on treatment decisions

More impact on treatment decisions

- Overall survival (mOS), Hazard Ratio (HR)
- Progression Free Survival (mPFS)
- **KEY DIFFERENTIATORS**
  Complete Response (CR) + Duration of Response (DOR)
- Depth of response
- Overall Response Rate (ORR)
- Time to response (TTR)

In addition to OS and PFS, CR rates, DOR, and depth of response are being recognized as important differentiators in head and neck cancer

Source: Internal Bicara market research, 2026

FICERA's TGF-β-driven tumor penetration enables deep and durable responses

Previously Demonstrated

TGF-β-driven tumor penetration

- Targeted inhibition of TGF-β in the tumor
- Tumor penetration of immune cells by breaking barriers in TME
- Increased immune activation

Deep responses

- Deeper responses observed at doses with greater TGF-β inhibition
- 80% of responders achieved a deep response at pivotal study dose

ASCO 2026

Durability and improved outcomes

- Consistent efficacy improvements across ~90 patients with extended follow-up
- Trend for improved DOR, PFS and OS at doses with greater TGF-β inhibition observed
- Deep responses translated to improved durability and long-term outcomes (PFS, DoR, OS)

TME, Tumor Microenvironment; **DOR**, Duration of Response; **PFS**, Progression-Free Survival; **OS,** Overall Survival

Thank You