BICARA THERAPEUTICS™

Fighting cancer with precision and power.



November 2026 Corporate Deck

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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 expectation for an interim analysis mid-2027; the timing of future data releases from our ongoing Phase 1/1b expansion cohorts, including an anticipated data release from the expansion cohort evaluating ficerafusp in patients with 3L+ mCRC (RAS/BRAF wild type MSS) in January 2027; the advancement of the FORTIFI-FLEX study and expectations for results in time for a potential U.S. approval; 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; our ability to scale and prepare for potential commercialization of ficerafusp alfa; the potential for U.S. regulatory approval and U.S. launch of ficerafusp alfa in 2028; the potential market opportunities for ficerafusp alfa in HPV-negative HNSCC, including the potential to grow the market beyond current projections, and potential expansion opportunities across other solid tumors; and our expected operating expenses and capital expenditure requirements. 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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or other events to be materially different from any future results, performance or other events expressed or implied by the forward-looking statements. Given these uncertainties, you should not place undue reliance on forward-looking statements. Our actual future results, performance or other events may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. Factors that could cause actual results to differ from those predicted in our forward-looking statements include, among others, risks and uncertainties related to product development, including delays or challenges that may arise in the development and regulatory approval of our current and future product candidates or programs; uncertainties as to the availability and timing of results and data from preclinical and clinical studies; the timing of and our ability to submit and obtain regulatory clearance for investigational new drug applications, initiate additional clinical trials, and submit new drug applications or biologics license applications; our ability to initiate and complete our current and expected clinical trials; our ability to establish and maintain collaborations, strategic relationships and supply arrangements, or that we will not realize the intended benefits from such relationships or arrangements; whether our cash resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; our ability to raise additional funding on favorable terms, or at all; the rate and degree of market acceptance and clinical utility of our product candidates; the ability and willingness of our third-party collaborators to continue research and development and manufacturing activities relating to our product candidates; the accuracy of our data analyses or estimates for the potential and market for our products; our ability, and the ability of our collaborators, to protect our intellectual property and to conduct activities for the development and commercialization of our candidates in view of third party intellectual property positions; our financial performance; our ability to retain and recruit key personnel; developments and projections relating to our competitors or our industry; changes in general economic conditions and global instability, in particular economic conditions in the markets on which we or our suppliers operate; changes in laws and regulations; and those risks and uncertainties identified in our filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and such other risks and uncertainties that may be described in subsequent filings we may make with the SEC.

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.

A clinical-stage biotechnology company developing targeted tumor modulators

BICARA THERAPEUTICS™

Developing bifunctional antibodies that combine tumor-targeting mechanisms with therapeutic modulation of the tumor microenvironment

Advancing ficerafusp alfa (FICERA), the **first and only EGFR-directed antibody bound to a TGF-β ligand trap,** with blockbuster potential in 1L R/M HPV-negative HNSCC

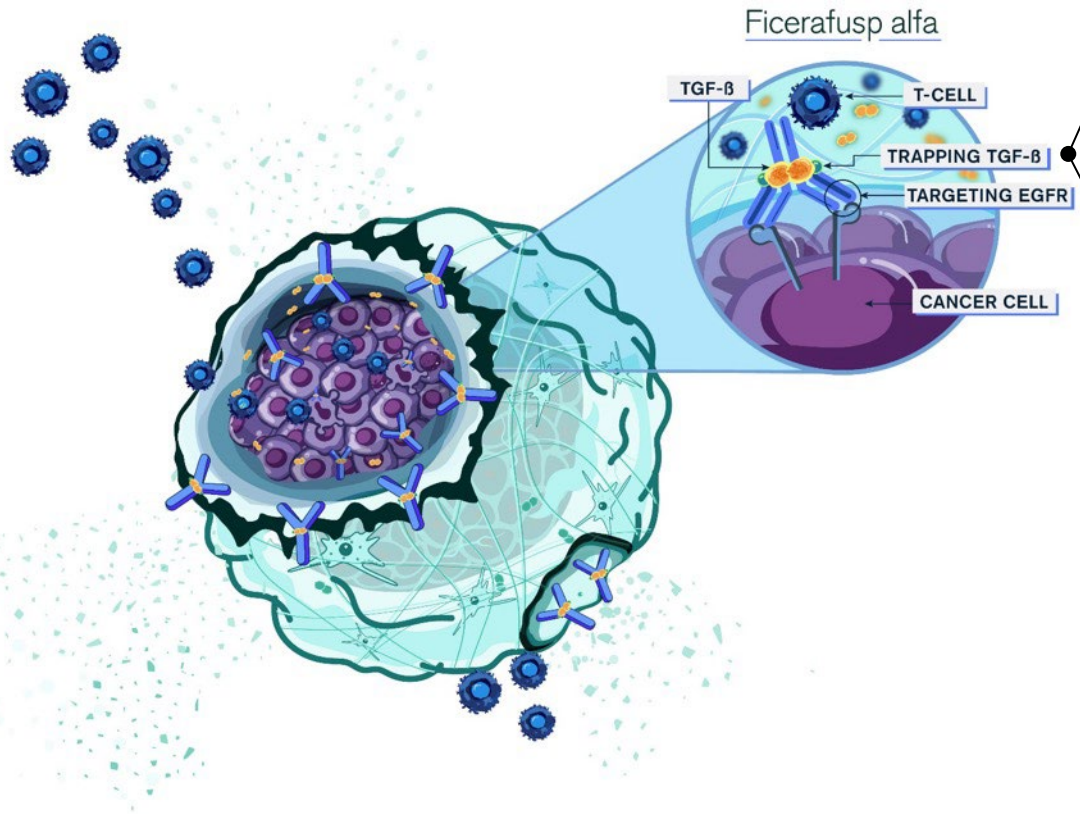
Signal-seeking in additional solid tumors with an EGFR x TGF-β biological fingerprint to explore FICERA's pipeline-in-a-product potential

EGFR, epidermal growth factor receptor; TGF-β, transforming growth factor-beta; 1L, first-line; R/M, recurrent or metastatic; HPV, human papilloma virus; HNSCC, head and neck squamous cell carcinoma

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**

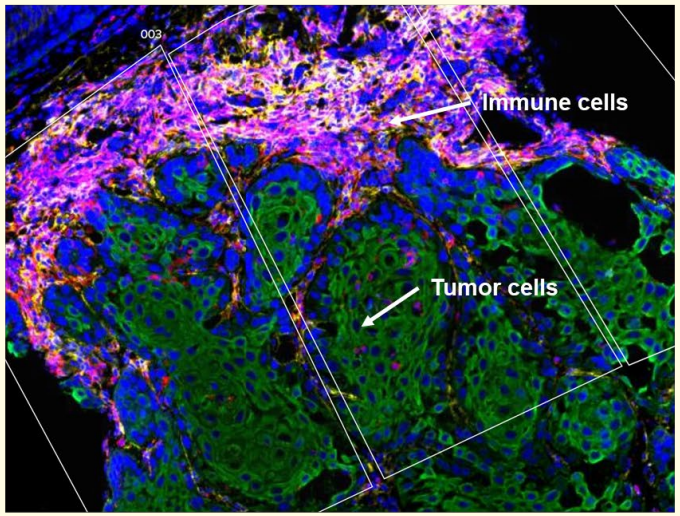
1. **Enables tumor penetration**
2. **Prevents resistance**

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

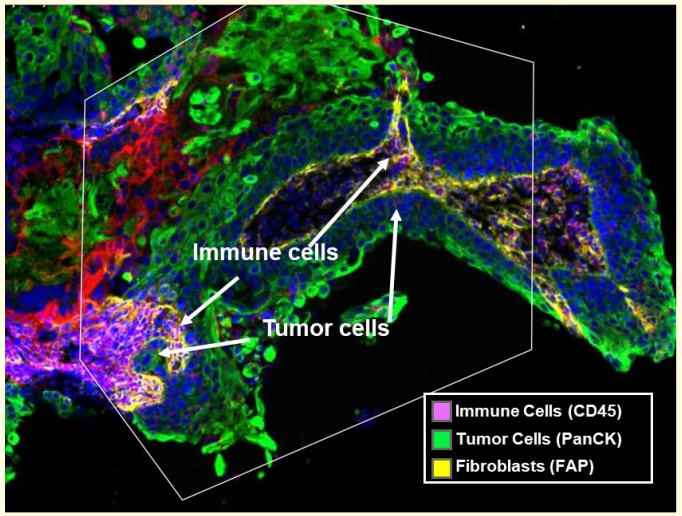
Following the science to establish a clinical foothold in HPV-negative HNSCC

HNSCC is a fibrotic, immunosuppressive solid tumor

Baseline



FICERA + Pembro (3wks)



Remodeling the TME in an HPV-neg patient in our Ph.1/1b study with a -84% PR

HPV-negative is a distinct and compelling clinical subset of HNSCC

Increased **EGFR** expression

Elevated levels of **TGF-β1** in serum

High rate of **therapeutic resistance**

Bedi, Atul, et al. Molecular cancer therapeutics (2012).

Bicara is redefining the treatment of head and neck cancer

BICARA THERAPEUTICS™

Developing FICERA, a bifunctional **EGFRxTGF-β** antibody designed to drive tumor penetration, for **1L R/M HPV-negative HNSCC**



1

Mechanistic approach rooted in causal biology

FICERA is a bifunctional antibody that blocks EGFR while inhibiting TGF-β in the tumor microenvironment, designed to drive **tumor penetration** and address the **causal biology of HPV-negative HNSCC**



2

Clinically validated profile

Phase 1b **data showed deep, durable responses**, with three-year overall survival that approximately doubles standard of care[1]



3

Large, underserved market

1L R/M HPV-negative HNSCC represents a **global commercial opportunity of ~$5B+ annually by 2030** in a setting of profound unmet need



4

Positioned for value creation

FORTIFI-HN01 is **substantially enrolled** to enable a topline interim analysis in **mid-2027** that could support potential U.S. approval

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; **NE**, not estimable; **Q2W**, every 2 weeks; **QW**, once weekly; **TGF-β**, transforming growth factor beta; **TME**, tumor microenvironment.

Executing a Strategic Development Plan for FICERA in 1L R/M HPV-Negative HNSCC

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

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): 11601445

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

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 Phase 1b clinical experience in 1L R/M HPV-negative HNSCC

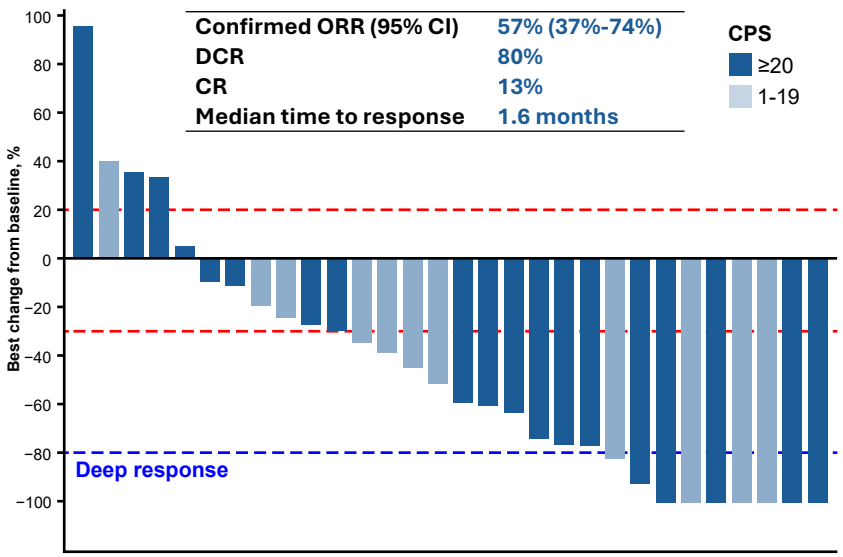
- Consistent safety, efficacy, **depth of response, and rapid time to response** supports further exploration for less frequent dosing schedule
- Data further **increase confidence in the pivotal study**

	Phase 1b data from exploratory higher dose, less frequent regimen	Phase 1b data from dose selected for pivotal study		
Metric	**2000mg Q2W*** **EE set (N=27)**	**1500mg QW*** **EE set (N=28)**	**750mg QW*** **EE set (N=30)**	**Pembrolizumab#** Current standard of care
Confirmed ORR % (N)	**48% (13/27)**	**54% (15/28)**	**57% (17/30)**	**~19%**
CPS 1-19	57% (8/14)	54% (7/13)	73% (8/11)	15%
CPS ≥ 20	38% (5/13)	53% (8/15)	47% (9/19)	23%
CR Rate % (N)	**30% (8/27)**	**25% (7/28)**	**13% (4/30)**	**~5%**
Deep Responses^ % (N)	**77% (10/13)**	**80% (12/15)**	**47% (8/17)**	**N/A**
Median PFS	**12.7 months**	**9.9 months**	**6.9 months**	**~3.2 months**
Median DoR	**NR (>12.8 months)**	**21.7 months**	**NR (>16.6 months)**	**~23.4 months**
Median OS	**NM (>12.7 months; >23.6 months in patients >2-year follow-up)†**	**21.3 months**	**NM (>19.4 months)**	**~9 months (HPV-negative)**
Median Time to Response	**1.6 months**	**1.4 months**	**1.6 months**	**2.1 months**

*Data snapshot as of March 31, 2026. ^Deep response refers to ≥ 80% tumor shrinkage from baseline. †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. #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. Data compiled from: Burtness, Barbara, et al. The Lancet 394.10212 (2019): 1915-1928; Vasiliadou, Ifigenia, et al. International Journal of Cancer 155.5 (2024): 883-893; Black, Christopher M., et al. Frontiers in Oncology 13 (2023): 1160144; European Medicines Agency (CHMP); Keytruda Assessment Report, Procedure No. EMEA/H/C/003820/II/0065 (2019).
EE = efficacy evaluable; ORR = objective response rate; CR = complete response; NR = not reached; NM = not mature

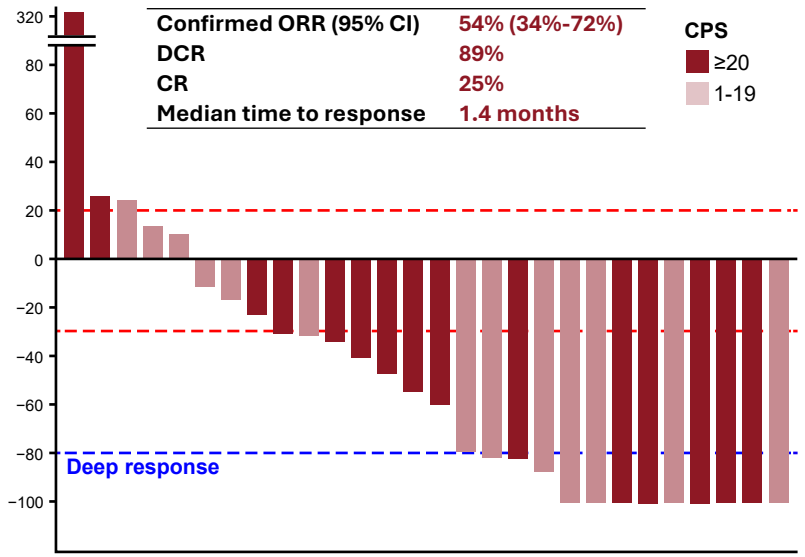
TGF-β inhibition drives rapid, deep responses and dose-dependent CR rates across cohorts

750mg QW



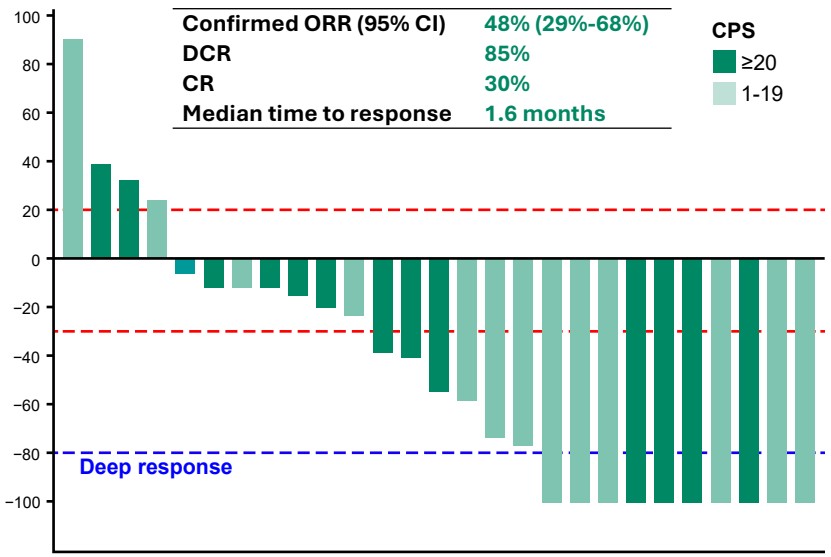
Deep response: 47% (8/17)

1500mg QW



Deep response: 80% (12/15)

2000mg Q2W



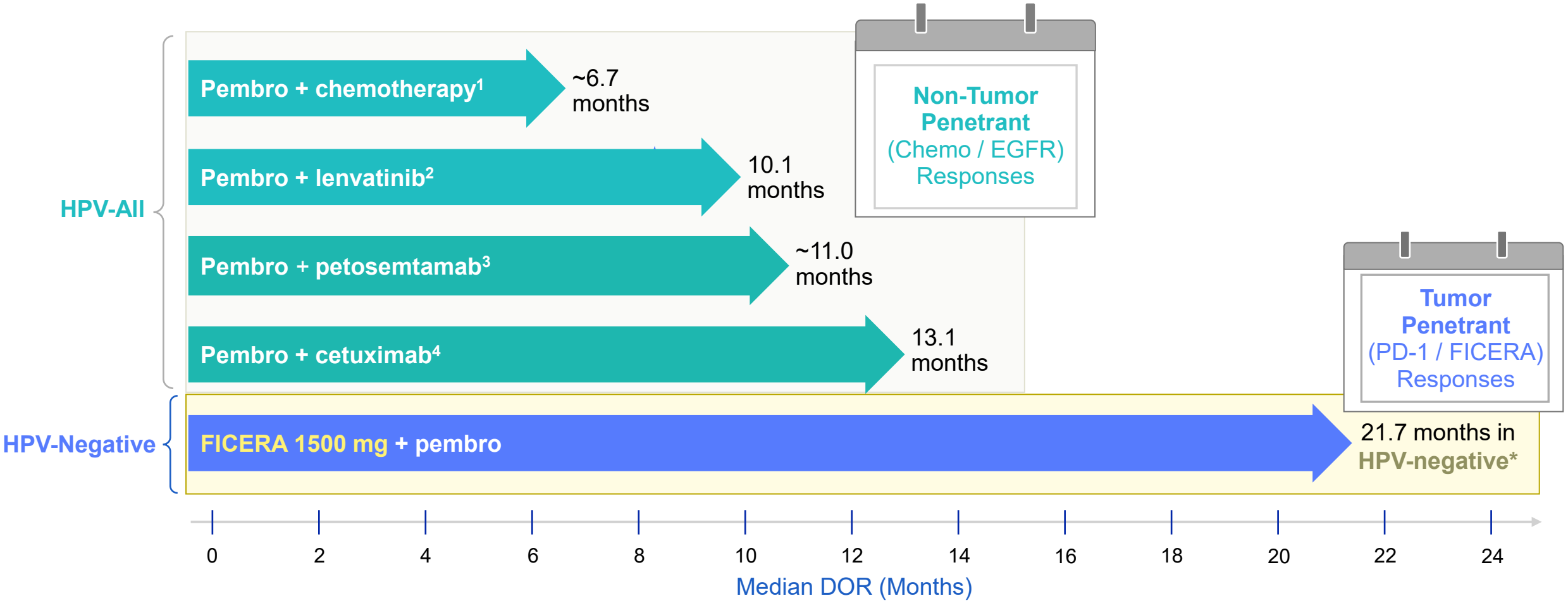
Deep response: 77% (10/13)

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

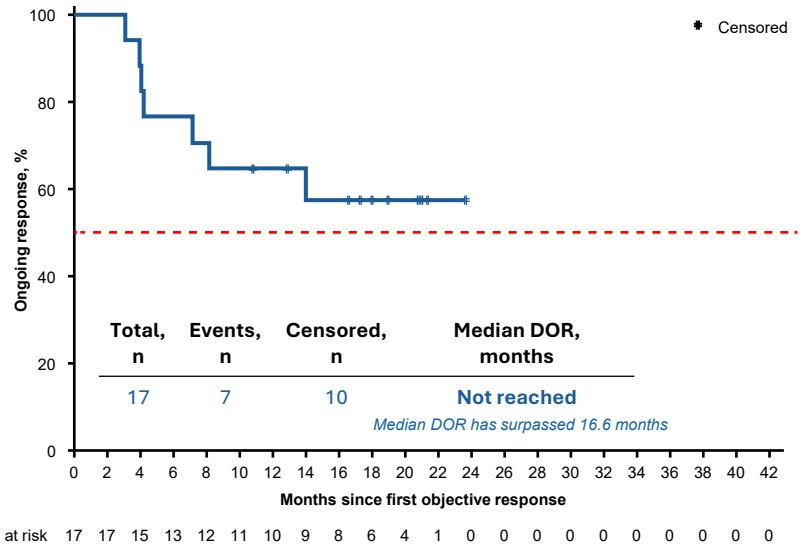
Median Duration of Response: Pembro Combinations in 1L R/M HNSCC



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

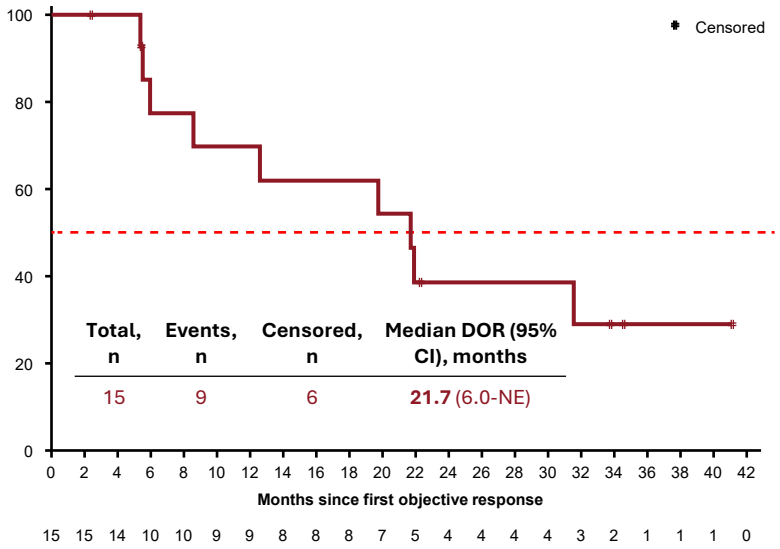
FICERA demonstrated clinically meaningful DOR across dose cohorts

750mg QW



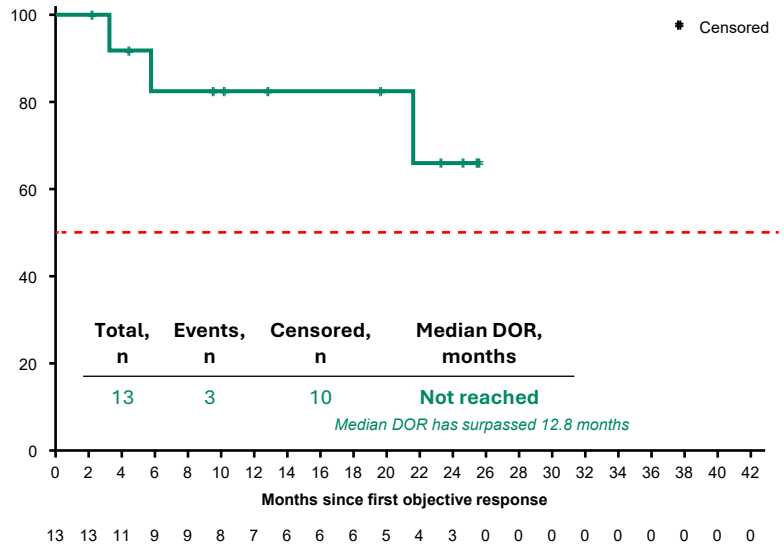
Median DOR: not yet reached; has surpassed 16.6 months

1500mg QW



Median DOR: 21.7 months

2000mg Q2W

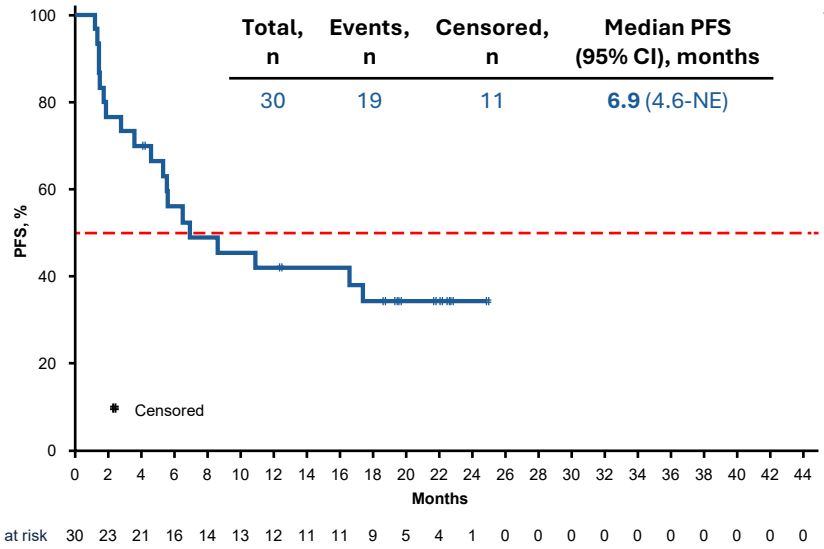


Median DOR: not yet reached; has surpassed 12.8 months

FICERA demonstrated clinically meaningful PFS across dose cohorts

750mg QW

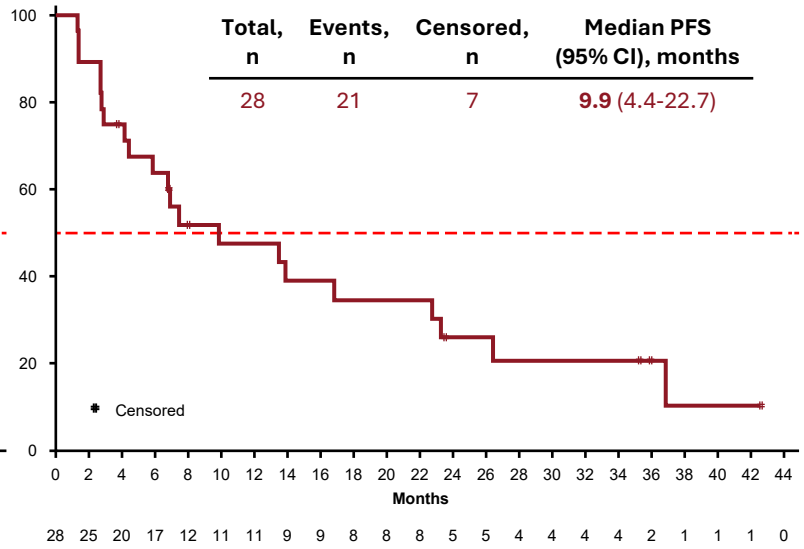
Total, n	Events, n	Censored, n	Median PFS (95% CI), months
30	19	11	**6.9** (4.6-NE)



Median PFS: 6.9 months

1500mg QW

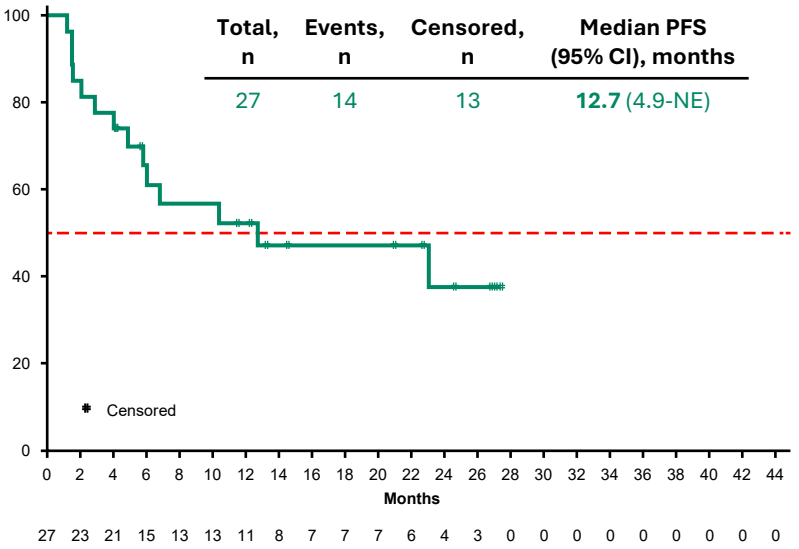
Total, n	Events, n	Censored, n	Median PFS (95% CI), months
28	21	7	**9.9** (4.4-22.7)



Median PFS: 9.9 months

2000mg Q2W

Total, n	Events, n	Censored, n	Median PFS (95% CI), months
27	14	13	**12.7** (4.9-NE)



Median PFS: 12.7 months

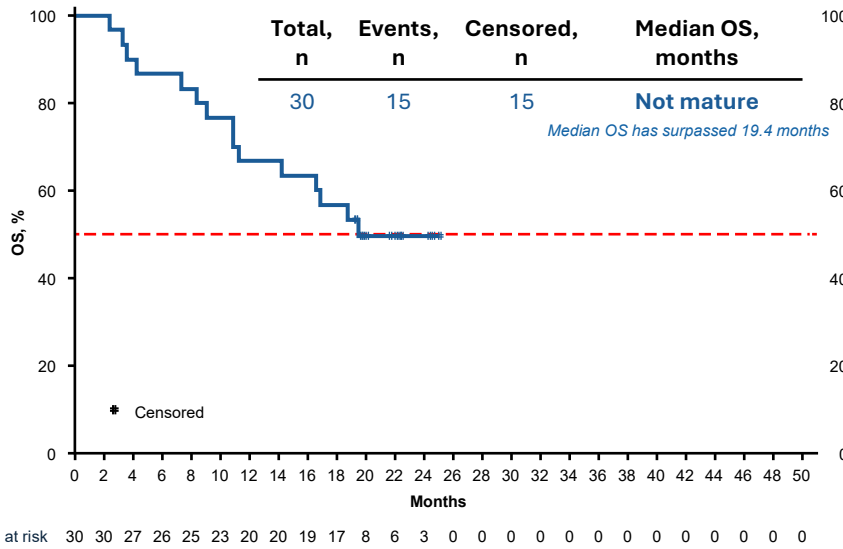
FICERA's median PFS of 9.9 months represents a **>3x increase** vs. pembrolizumab (~3.2 months[1])

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

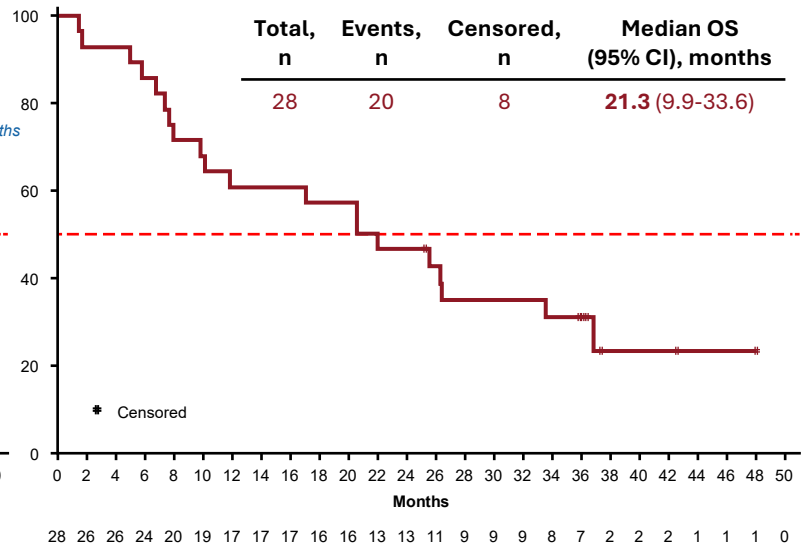
FICERA demonstrated clinically meaningful OS across dose cohorts

750mg QW



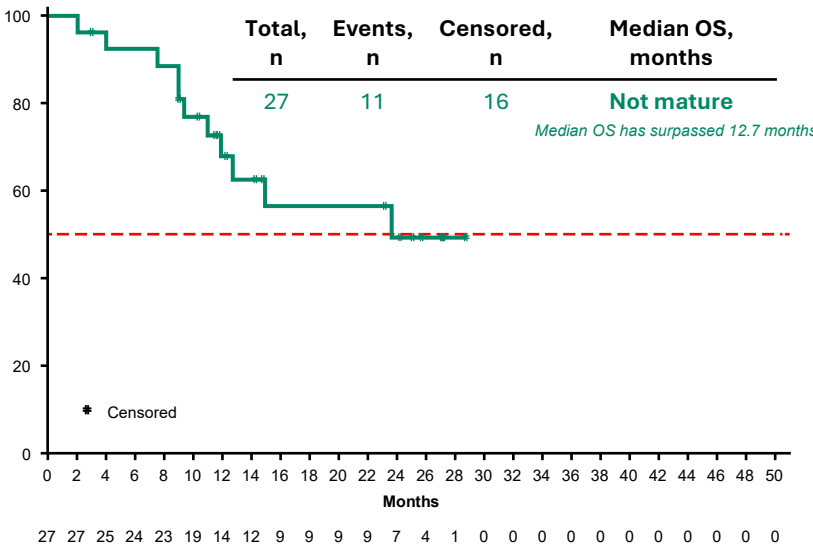
Median OS: not yet mature; has surpassed 19.4 months

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:

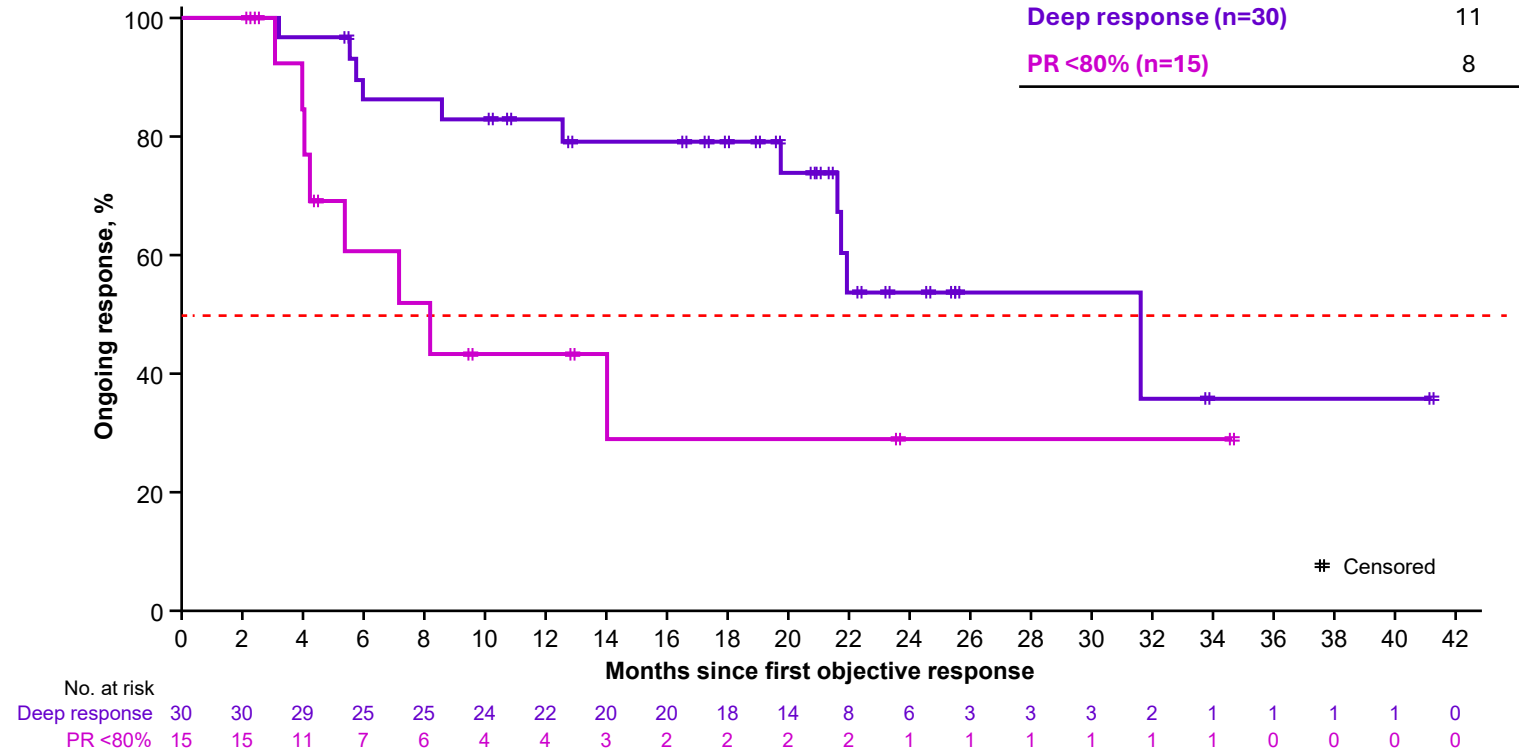
FICERA delivered 54-73% ORR, more than 3x pembrolizumab monotherapy (~15%)[1]

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.

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)

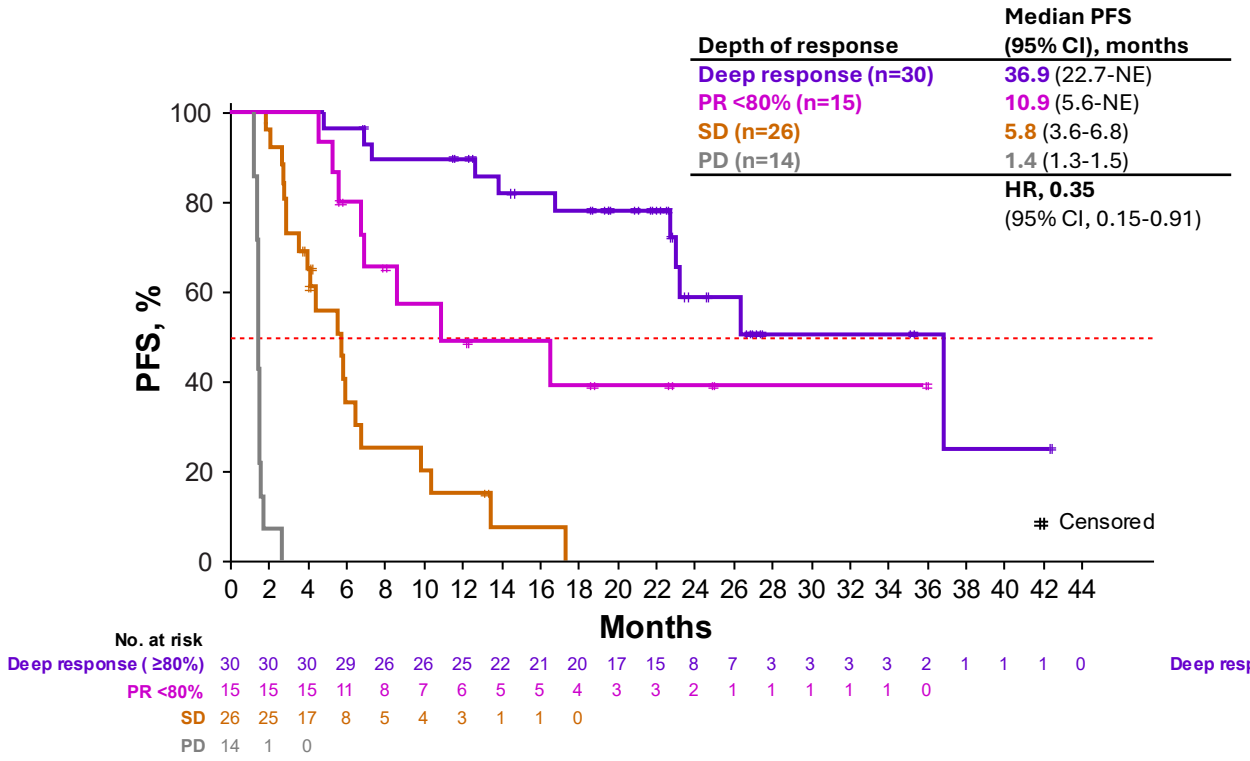


N=45 across 750mg, 1500mg, 2000mg dose cohorts

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

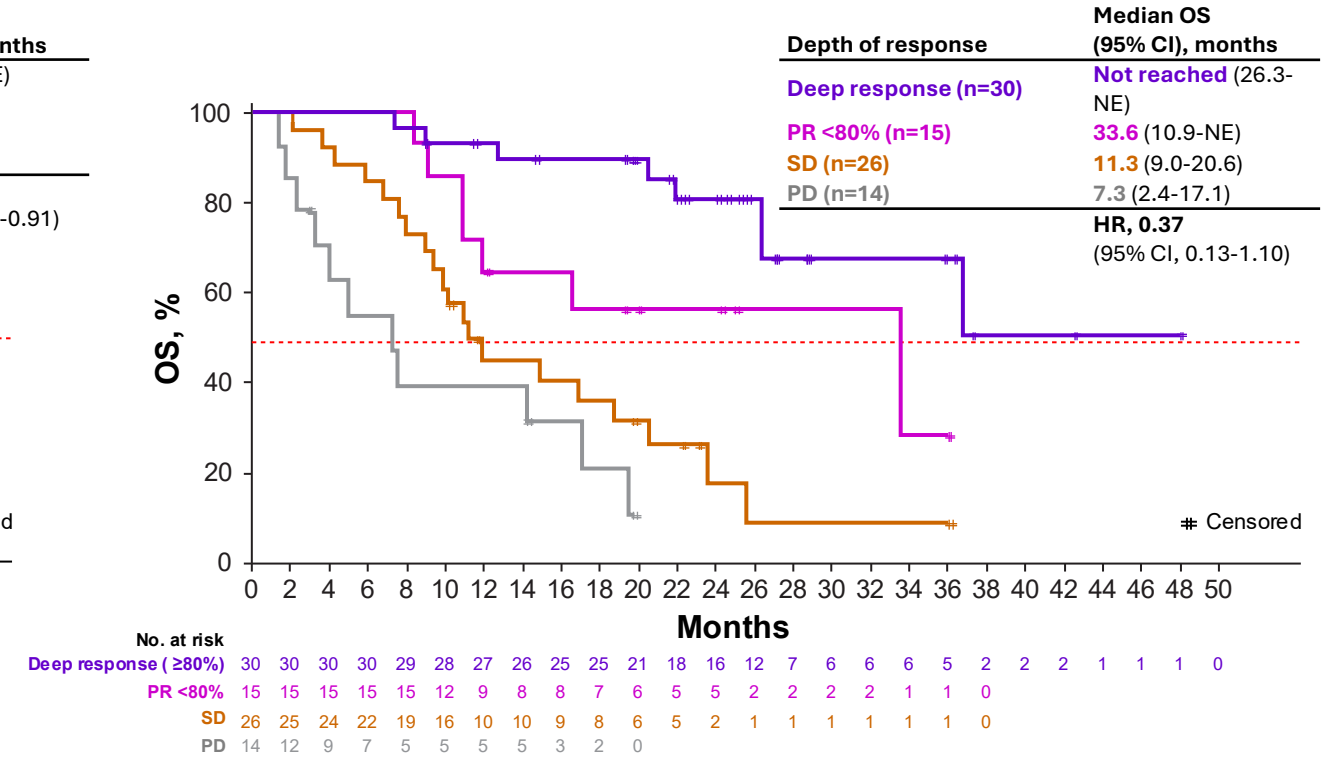
Data snapshot: March 31, 2026

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.

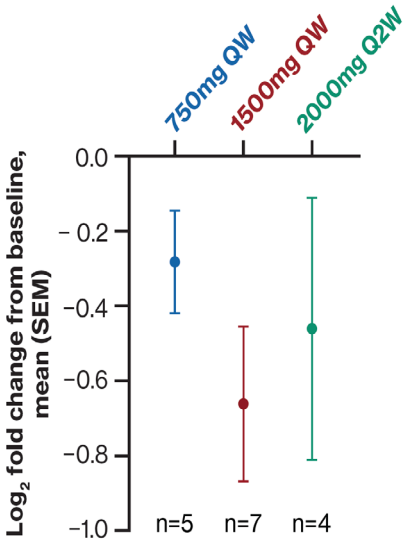
N=45 across 750mg, 1500mg, 2000mg dose cohorts

Data snapshot: March 31, 2026

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

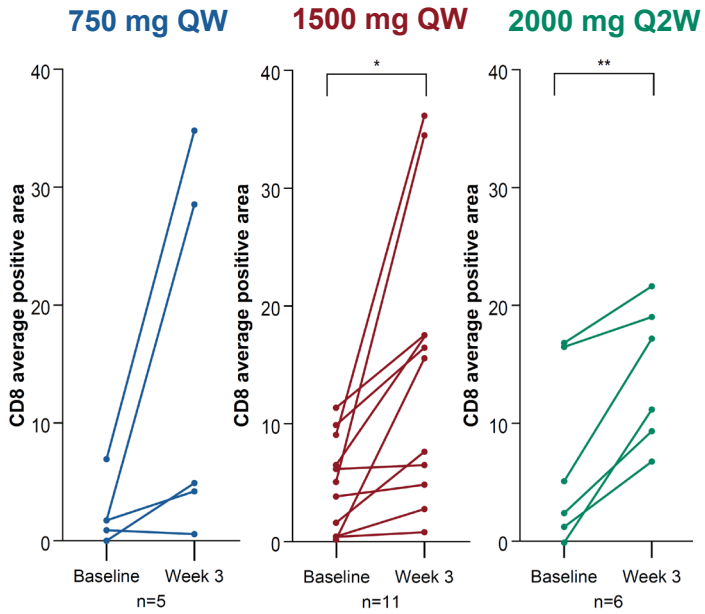
TGF-β Inhibition

pSMAD2 ⬇



Tumor Penetration

CD8+ T Cell Tumor Infiltration

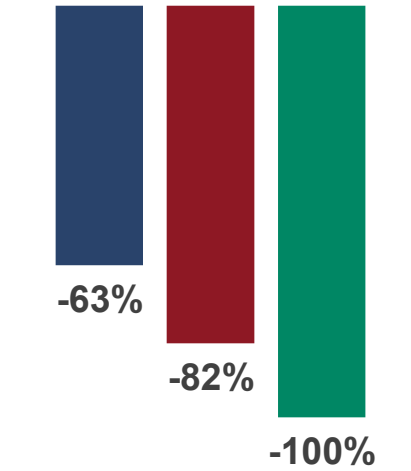


Plots show mean with SEM. Mann-Whitney Test from Log2 Baseline adjusted *p≤.05, **p ≤.01

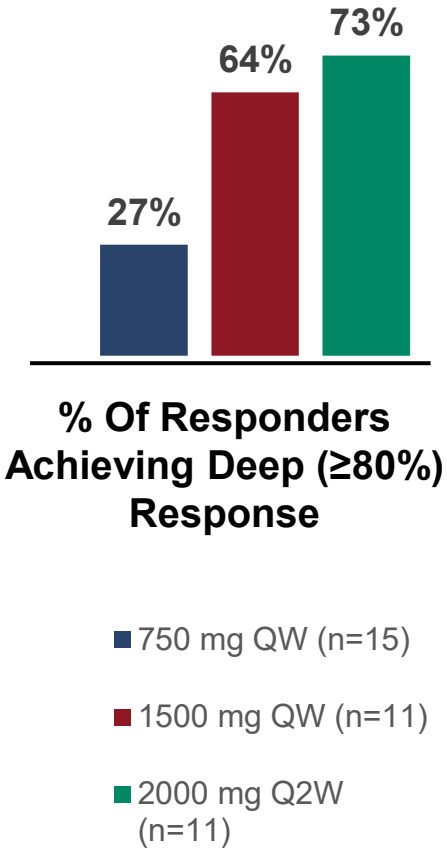
Increases in TGF-β inhibition directly in the TME enabled greater tumor penetration to **drive deeper and more durable responses**

Depth of Response At 24-Weeks

Median Depth of Response



% Of Responders Achieving Deep (≥80%) Response



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.

Why our data, and the context behind them, matter

FICERA's Phase 1b enrolled the patients who are hardest to treat

	1500 mg QW pivotal-dose cohort[1] N=30	Why it matters
HPV status	**100%** HPV-negative	**HPV-negative patients are a poorer-prognosis population in head and neck cancer, and the only population enrolled in FORTIFI-HN01[2]**
Site of disease	**30%** locoregional only **47%** locoregional + distant **23%** distant only	**Locoregional recurrence is typically harder to treat, as previously irradiated tissue can limit drug delivery[3]**
PD-L1 expression	**50%** CPS 1–19 **50%** CPS ≥20	**Checkpoint inhibitors have historically been least effective in lower-CPS disease[4]**
Tumor burden	**47%** >50 mm **27%** >70 mm	**Larger, bulkier tumors are less likely to achieve a deep response[5]**

FICERA: bifunctional **EGFRxTGF-β** antibody **purpose-built for HPV-negative disease**, the only population enrolled in **FORTIFI-HN01; interim analysis expected mid-2027**

1) Baseline characteristics, FICERA 1500 mg QW + pembrolizumab, Phase 1b, 1L R/M HPV-negative HNSCC; data snapshot March 31, 2026 (ASCO 2026). Tumor burden is the sum of target lesion diameters at baseline.; 2) Ang KK, et al. N Engl J Med. 2010;363:24–35; 3) Belfiore MP, et al. Biomedicines. 2024;12:2080. Ramia P, et al. Clin Med Insights Oncol. 2022;16:11795549211036898.4) Burtness B Lancet. 2019;394:1915-1928. Burtness B, et al. J Clin Oncol. 2022;40:2321–2332. Haddad R, et al. J Clin Oncol. 2023;41:2166-2180; 5) Inoue H, et al. Pre-treatment tumor size impacts on response to nivolumab in head and neck squamous cell carcinoma. Auris Nasus Larynx. 2020 Aug;47(4):650-657. doi: 10.1016/j.anl.2020.01.003. Epub 2020 Feb 5. PMID: 32035695.

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

Key principles guiding less frequent dose exploration for FICERA

Mechanistic Differentiation

Maintain FICERA's hallmark TGF-β inhibition at a less frequent dose while being responsive to the tumor as it shrinks

Meaningful Clinical Data

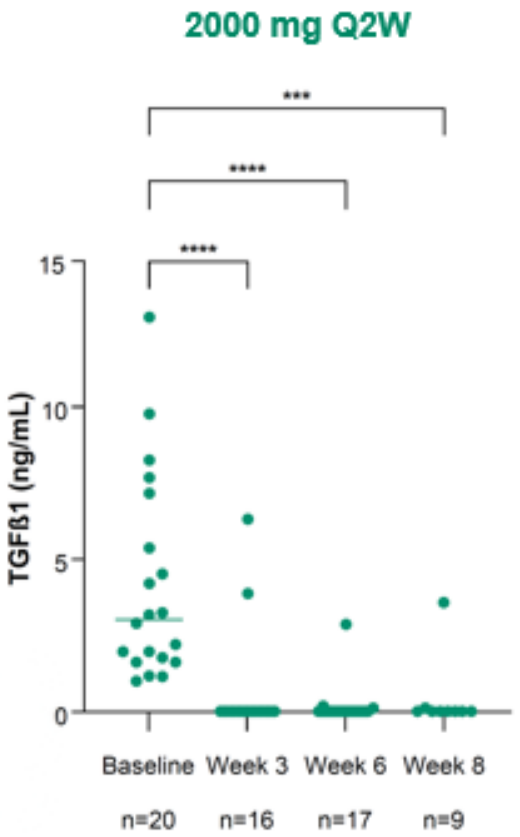
Rapid and deep responses that yield **durability and long-term outcomes** due to TGF-β inhibition

Patient Optionality

Enhance convenience and patient flexibility by **offering less-frequent dosing option** in combination with pembrolizumab

Totality of data support development of a loading and Q3W maintenance regimen for FICERA

TGF-β neutralization (plasma) at 2000mg Q2W FICERA plus pembrolizumab



****p<.0001;***p<.001, ** p<.01, *p<.05

Mechanistic Differentiation

Rapid tumor penetration and shrinkage with TGF-β targeting creates a natural opportunity to extend the dosing interval while preserving potency

Meaningful Clinical Activity

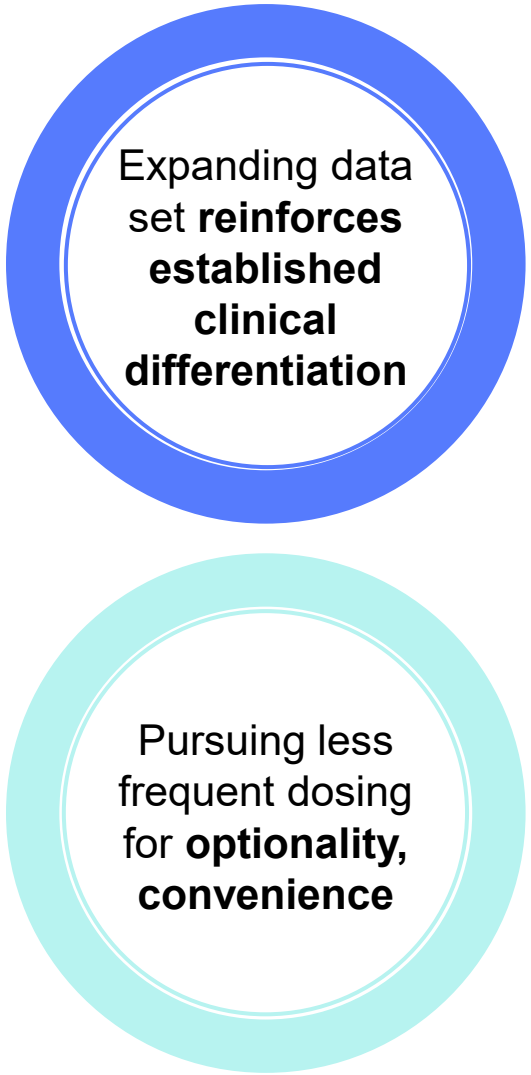
Integrated clinical and PK/PD modeling data support that deep, durable responses can be maintain with loading and maintenance

Advancing an Alternate Dosing Regimen Strategy

Initiated FORTIFI-FLEX alternate dose study to evaluate FICERA + pembrolizumab in 1L R/M HPV-negative HNSCC, and expect to have results from this study by the time of a potential U.S. approval in 1L R/M HPV-negative HNSCC

Bicara Therapeutics data on file; data snapshot March 31, 2026
PK/PD = pharmacokinetic/pharmacodynami

Totality of Phase 1b data across all doses of FICERA supports mechanism-driven clinical differentiation



Observed consistent, generally well-tolerated safety profile and rapid, deep responses in Phase 1b cohorts from 1500mg QW (ongoing Phase 3 pivotal study dose) and 2000mg Q2W FICERA (exploratory cohort to inform alternate dose regimen)

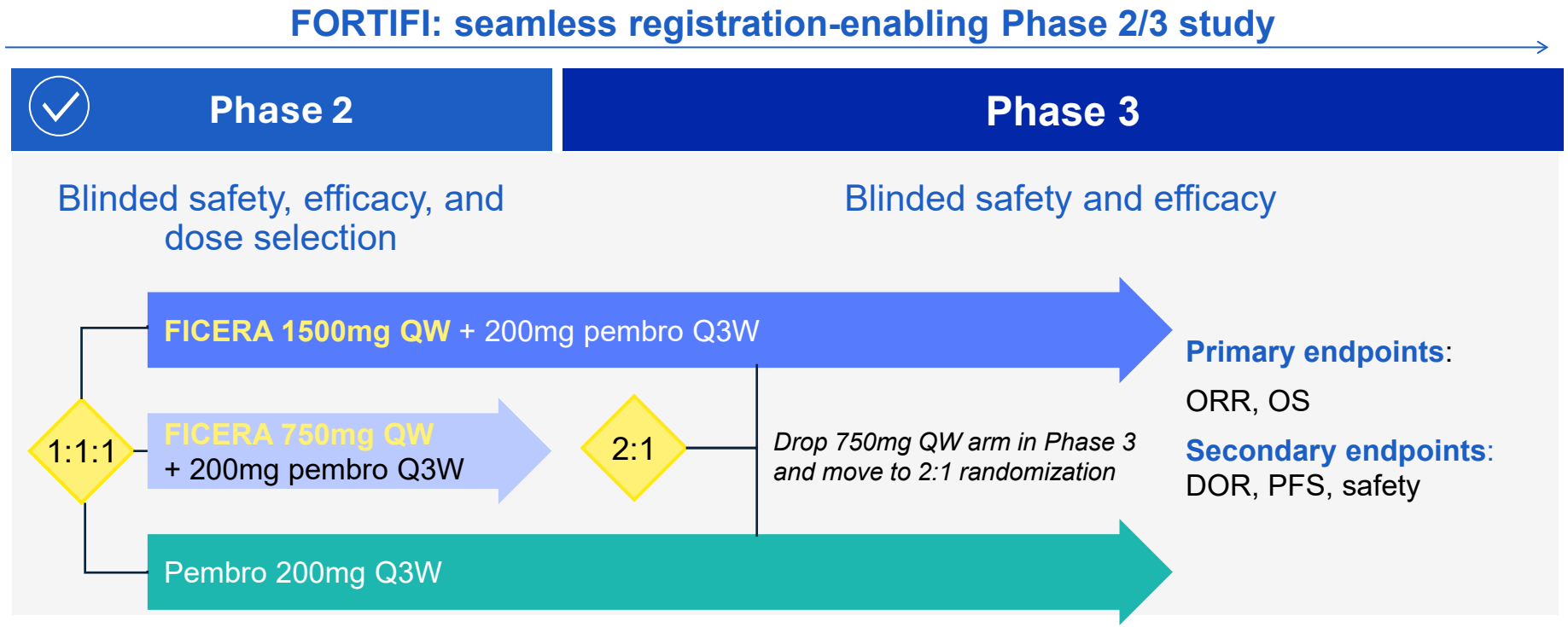
Deep responses translated into durable long-term outcomes across DOR, PFS, and OS

Sustained TGF-β inhibition, immune activation, tumor penetration, and deep responses observed at 1500mg QW and 2000mg Q2W FICERA, supporting development of less frequent dosing regimen

Growing body of PK, translational, exposure-response, and clinical data support development of loading and Q3W maintenance regimen designed to optimize efficacy, safety, and schedule; pursuing regulatory alignment with aim to generate data in time for potential US launch

FICERA, a potential best- and first-in-class EGFR-directed antibody combined with a TGF-β ligand trap, has demonstrated improved outcomes in HPV-negative HNSCC

Pivotal FORTIFI-HN01 trial design has enabled accelerated dose selection and efficient Phase 3 initiation

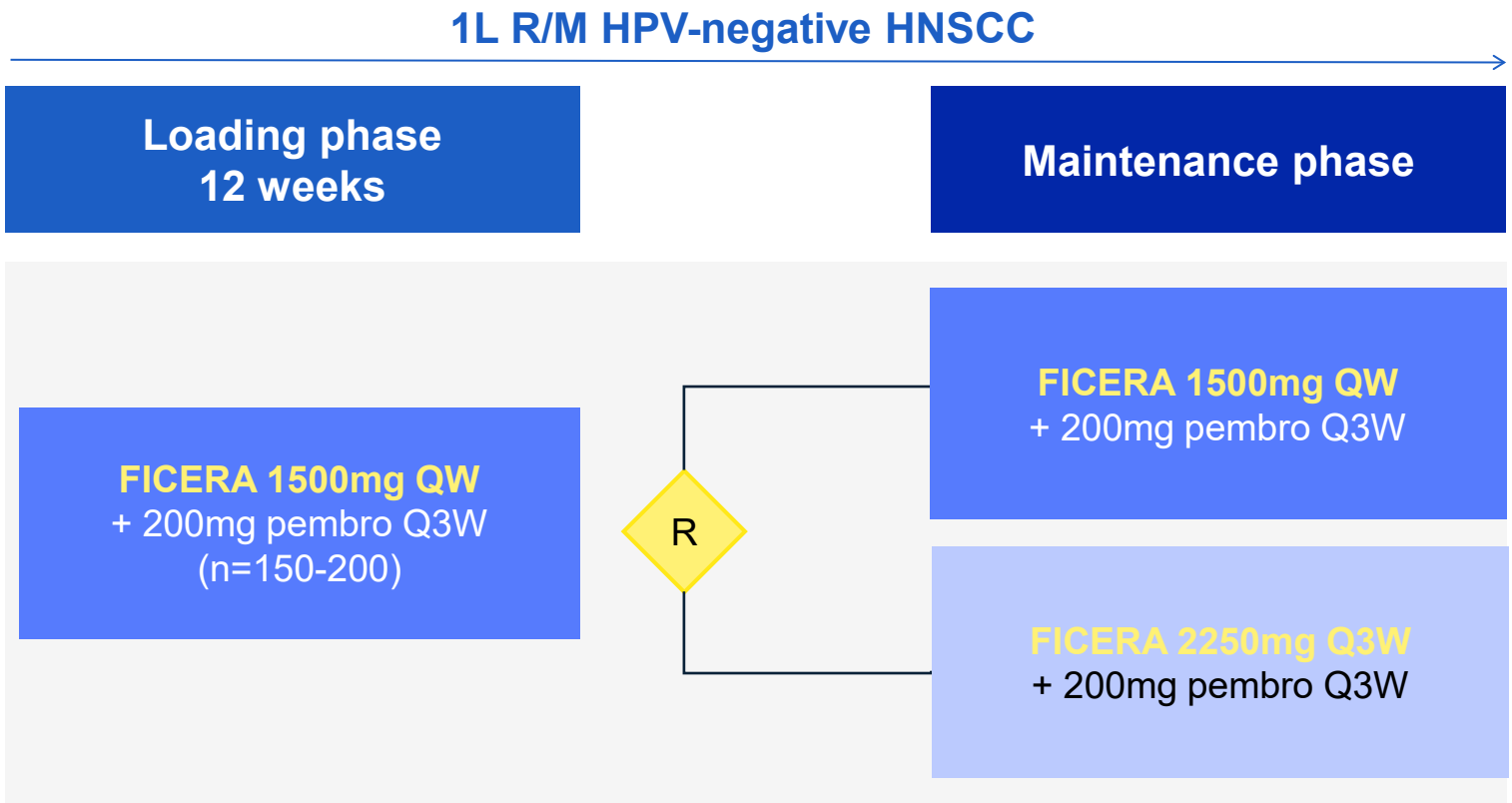


Phase 3 initiated and currently enrolling with 1500mg QW FICERA

- Patients enrolled at 1500mg FICERA QW in the Phase 2 portion continue treatment and contribute to pivotal efficacy analysis

CPS, combined positive score; Q3W, every three weeks; ORR, objective response rate; DOR, duration of response; PFS, progression-free survival; pembro, pembrolizumab

FICERA's alternate dosing regimen study to expand optionality and convenience for patients and providers



Primary endpoint:

Progression free survival

Results expected by the time of a potential U.S. approval in 1L R/M HPV-negative HNSCC

QW, every week; Q3W, every three weeks; R, randomize

Preparing for Commercial Success

A $5B+ annual global market that FICERA is built to lead, and to grow

HPV-negative HNSCC carries the poorest outcomes and the fewest effective options today

$5B+
projected annual global HNSCC sales by 2030[1]

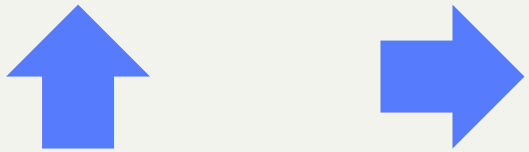
~50K
HPV-negative patients newly diagnosed each year in the US, EU5 and Japan[2]

~18K
of those patients in the US alone[2]

An underserved population

1. Limited response rates
2. Limited durability
3. HPV-negative status is prognostic of worse outcomes

FICERA can grow the market beyond current projections



Higher response rates

Longer duration of therapy

Deep, durable responses drive OS

Deep responses
25% CR; 80% of responders ≥80% shrinkage[3]

Durable responses
mDOR ~22 mo; >2.5 yrs in deep responders[3]

Potential survival benefit
~2x the 3-year survival seen historically with pembrolizumab[3]

Tumor penetration *driven by the synergy between TGF-β inhibition and immunotherapy*

FORTIFI-HN01 pivotal trial is designed to confirm this benefit

1. Evaluate Pharma 2025. 2. Tessellon patient flow modeling; SEER; country-specific registries; literature review. 3. FICERA + pembrolizumab, three-year follow-up, ASCO 2026; CR, depth and mDOR at 1500 mg QW; deep-responder DOR pooled across all three dose cohorts. 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.

Physician conviction is building

Market research shows a meaningful shift in how physicians view FICERA over the past year

	2025 physician view		2026 physician view
Treatment approach	HPV+ and HPV- inclusion slightly favored	→	**HPV- seen as a distinct disease that may benefit from a targeted approach**
Efficacy	Value of deeper responses not yet appreciated	→	**CR and durability cited as key decision drivers**
Mechanism	Limited understanding of EGFRxTGF-β as differentiated MOA	→	**TGF-β and tumor penetration seen as a reason to believe**
Dosing	Less-frequent dosing preferred over weekly	→	**FORTIFI-FLEX seen as a meaningful step toward dosing flexibility**

A Commercial leadership team built to execute

50+

collective new product launches across our commercial leadership team, now in place

Underway

- ✓ Go-to-market strategy
- ✓ Disease education
- ✓ Payer and access strategy
- ✓ Data and analytics infrastructure

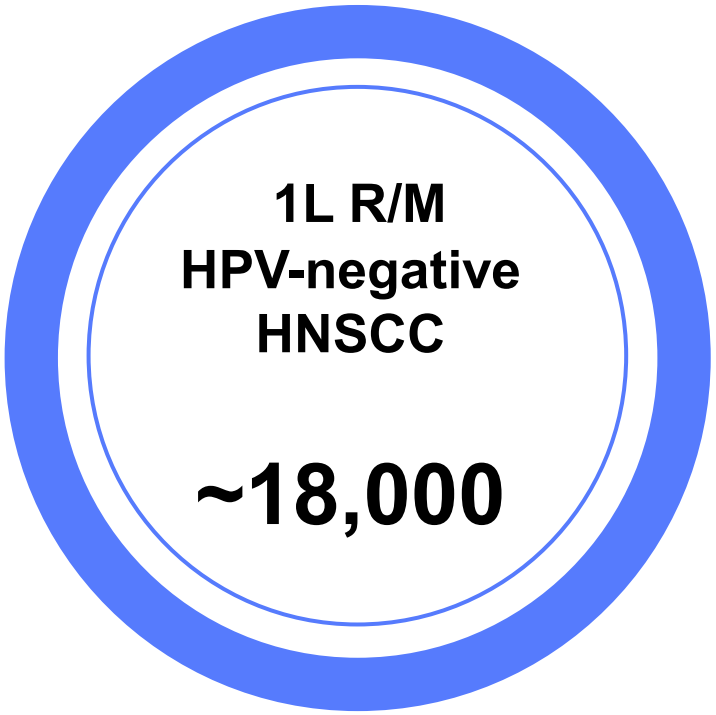
A market large enough to sustain multiple entrants, **with FICERA positioned to earn a winning share**

Source: Internal data, primary physician market research (Q3 2026)

Expanding FICERA's Potential While Maintaining Financial Discipline

Broader opportunity for FICERA in head and neck cancer

Registration-enabling Phase 3 ongoing



Multiple expansion opportunities representing ~50,000 patients in HNSCC (U.S. incidence)

~26,000

Locally Advanced
HPV-negative HNSCC

Earlier-line setting

~4,000

CPS < 1
1L R/M HPV-negative HNSCC

R/M subsegment

~2,000

HPV-positive Smokers
1L R/M HNSCC

R/M subsegment

~1,000

Rapidly Recurrent*
1L R/M HPV-negative HNSCC

R/M subsegment

Source: Bicara market research, represents annual incidence in U.S. SEER data; Tessellon patient flow modeling
*Patients who progressed within 6 months after multimodal treatment for locally advanced disease

Known EGFR, TGF-β biological fingerprint provides strong rationale for FICERA expansion potential across other solid tumors

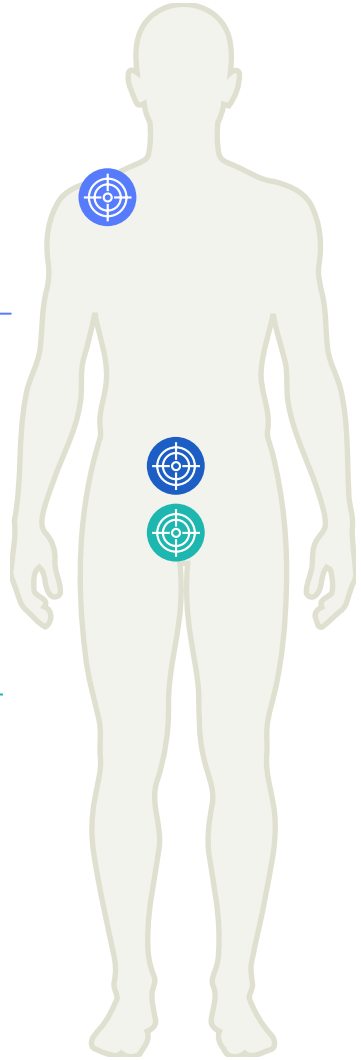
FICERA has demonstrated efficacy in other solid tumors

Cutaneous squamous cell carcinoma (cSCC)

Phase 1b expansion cohort evaluating FICERA monotherapy in patients with 2L+ cSCC **showed single agent activity** with an ORR of 30% (7/23 patients) and median PFS of 7.0 months[1]

Squamous cancer of the anal canal (SCAC)

Phase 1b expansion cohort evaluating FICERA + pembrolizumab in patients with 2L+ SCAC **showed activity** with an ORR of 29% (8/28 patients), **including in patients with liver metastases**, and median PFS of 2.9 months[2]



FICERA is being evaluated in mCRC

Metastatic colorectal cancer (mCRC)

Phase 1b expansion cohort assessing **FICERA as monotherapy and in combination with pembrolizumab** in patients with 3L+ mCRC (RAS/BRAF wild type MSS)

1) Kaczmar, Sherman, et al; Abstract CT034: Dose expansion results of single agent ficerafusp alfa (BCA101), a bifunctional EGFR/TGFβ inhibitor in patients with metastatic or advanced cutaneous squamous cell carcinoma (CSCC). Cancer Res 15 April 2025; 85 (8_Supplement_2): CT034; 2) Van K. Morris et al., Preliminary phase 1/1b dose expansion results of the bifunctional EGFR/TGFβ inhibitor ficerafusp alfa (BCA101) with pembrolizumab in patients with squamous cell carcinoma of the anal canal.. J Clin Oncol 43, 4-4(2025).

ORR, overall response rate; PFS, profession-free survival

Expansion to 3L+ MSS RASwt metastatic colorectal cancer (mCRC)

Initial Ph. 1/2 Proof of Concept Study

Unresectable mCRC:

- **2-3 previous lines**
  - Anti-EGFR is not the last line of treatment
  - Received prior biologics i.e. anti-VEGF
- **Confirmed RAS/BRAF wt and MSS**
- **ECOG 0-1**

Randomized 1:1

FICERA
N ~20

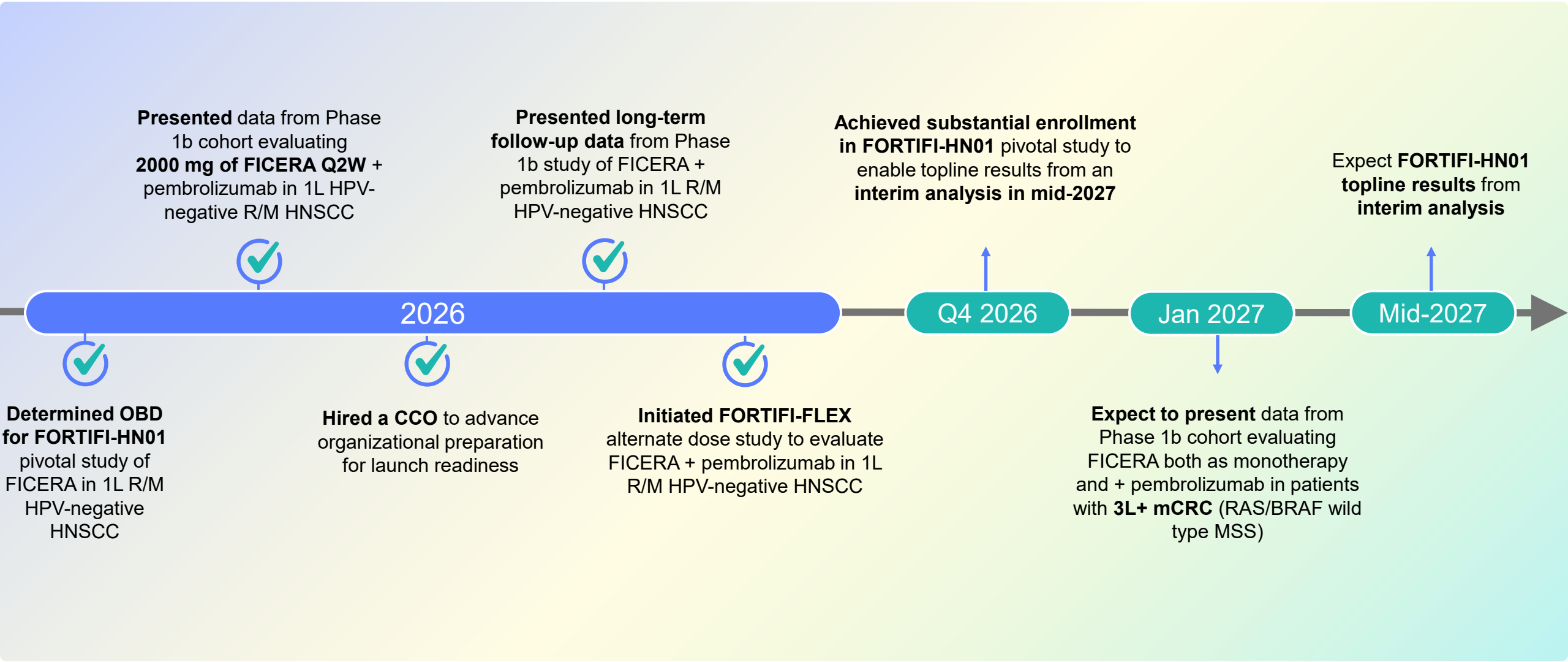
FICERA + pembro
N ~20

Primary aims: safety, tolerability, and initial efficacy (ORR/DCR)

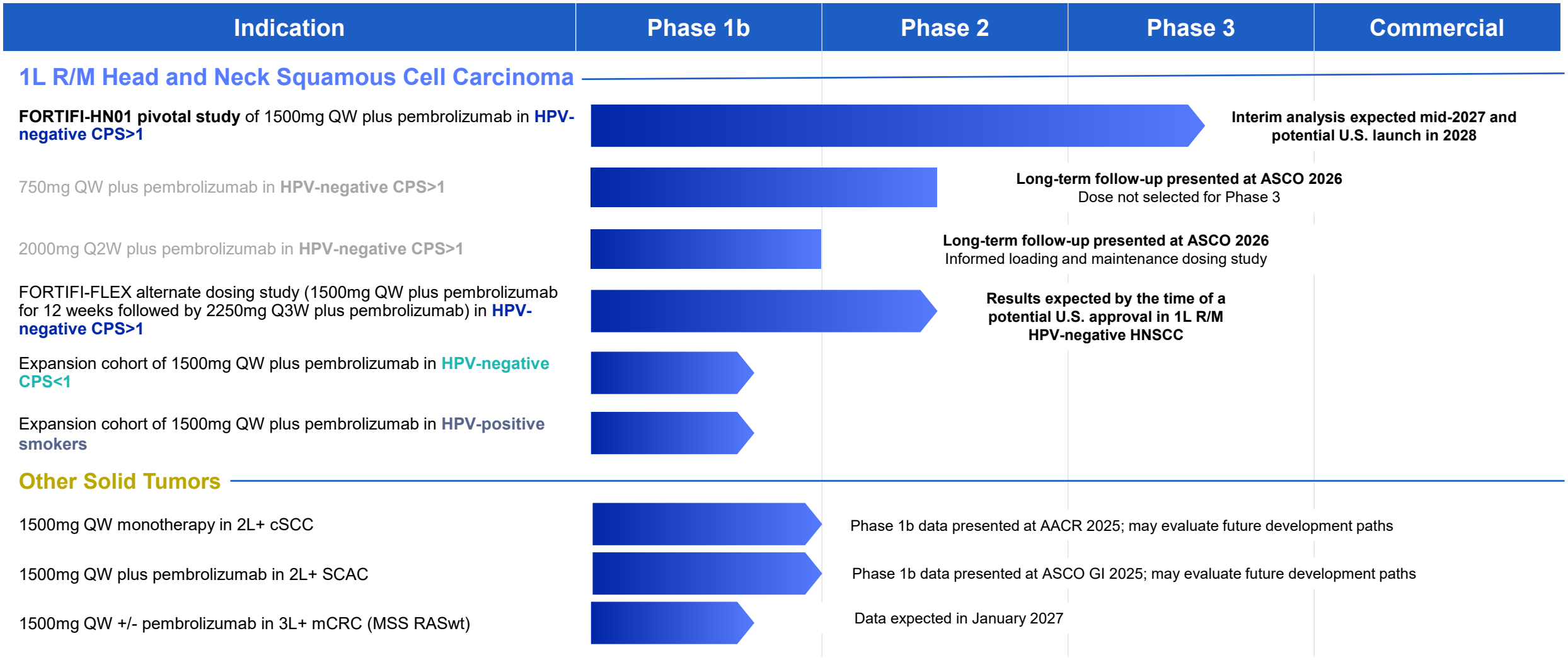
Unmet need: Current approved treatment options in 3L+ mCRC demonstrate 2 - 6% ORR and less than 6-month PFS[1,2,3]

1. Prager, et al. New England Journal of Medicine (2023).
2. Mayer, et al. New England Journal of Medicine (2015).
3. Dasari, et al. The Lancet (2023).

Anticipated key milestones to build long-term value



Maximizing the franchise value of FICERA



BICARA THERAPEUTICS™

Thank You

