BICARA THERAPEUTICS™

# Fighting cancer with precision and power.

**May 2026 Corporate Deck**

# 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 the trial to be substantially enrolled by the end of the year and 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 the second half of 2026; the initiation of an alternate dose study in the third quarter of 2026 to evaluate a loading and every-three-week maintenance dosing regimen of ficerafusp alfa and expectations for results in time for potential U.S. accelerated 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 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 a known EGFR x TGF-β biological fingerprint to explore FICERA's pipeline-in-a-product potential

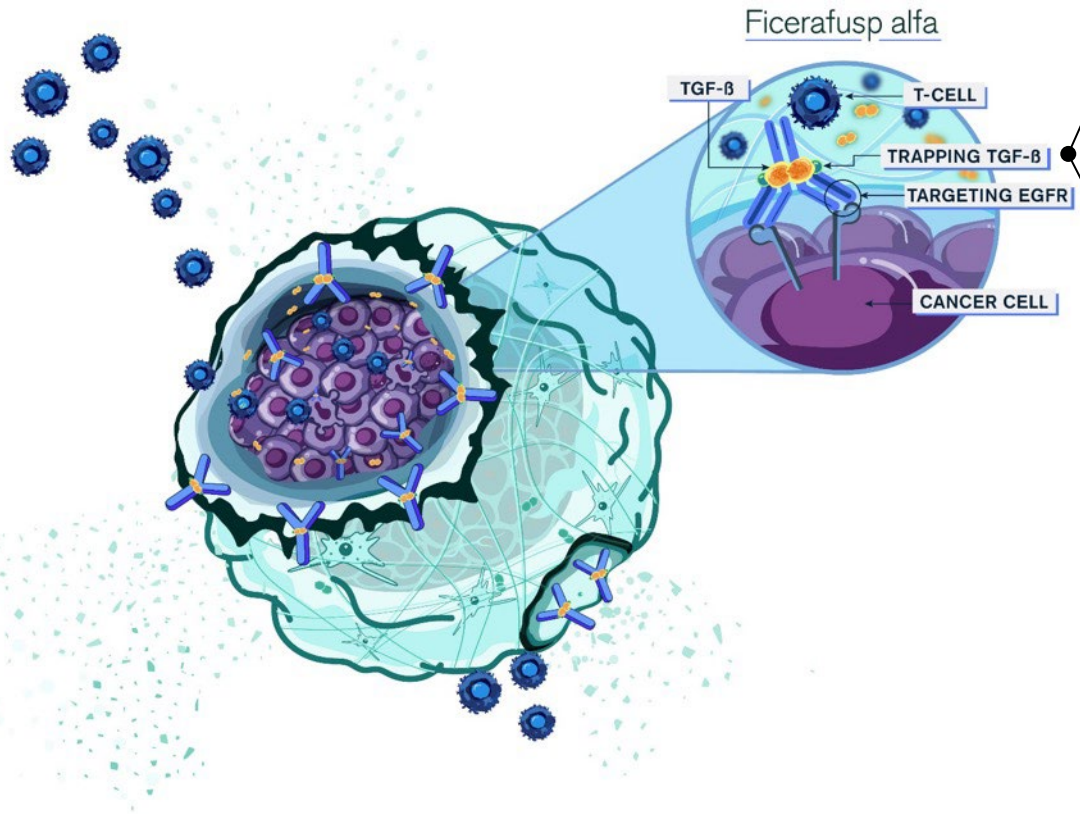


EGFR, epidermal growth factor receptor; TGF-β, transforming growth factor-beta; 1L, first-line; R/M, recurrent or metastatic; HPV, human papilloma virus; HNSCC, head and neck squamous cell carcinoma

# 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**

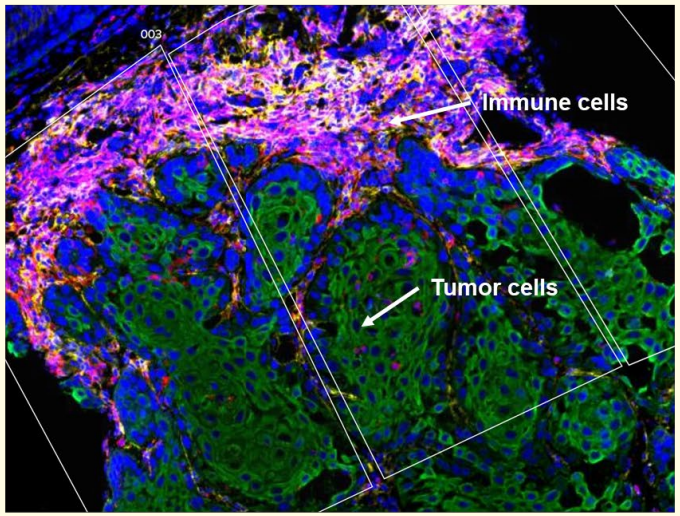


Boreddy SR, et al. Cancer Res. 2023;83(11): 1883-904.

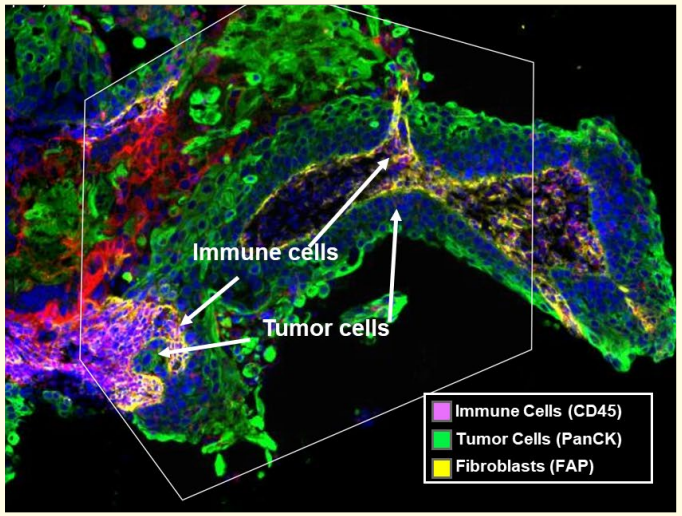
# Following the science to establish a clinical foothold in HPV-negative HNSCC

## 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

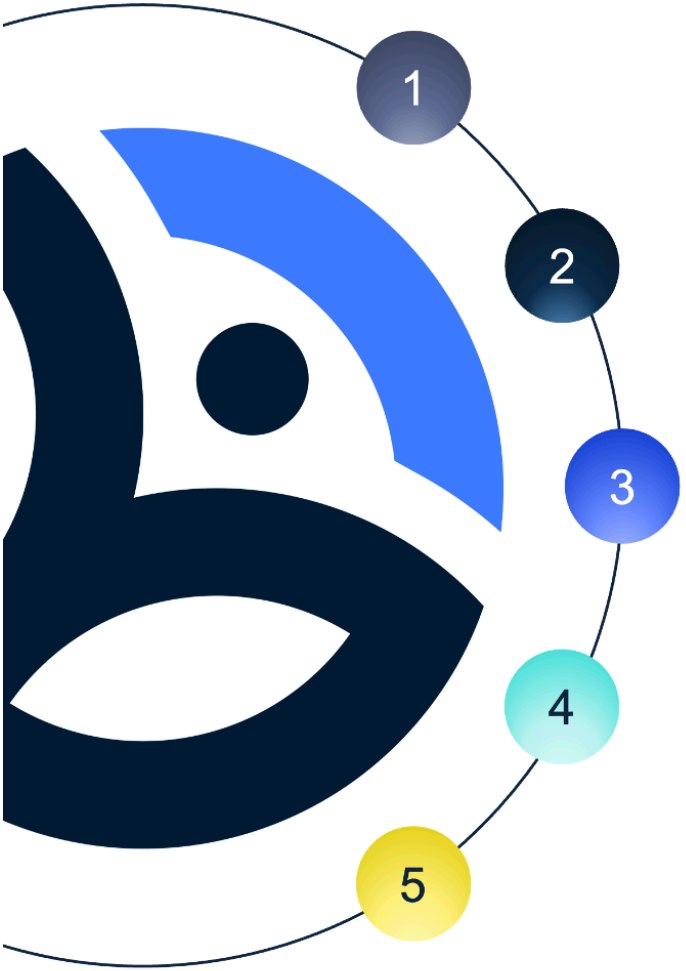
Elevated levels of **TGF-β1** in serum

High rate of **therapeutic resistance**



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

# Building momentum toward a potential breakthrough in HPV-negative HNSCC




1. **Differentiated overall survival representing a ~2x increase vs. standard of care[1] and generally well-tolerated safety out to three years at pivotal study dose**

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

3. **Expect to be substantially enrolled in FORTIFI-HN01 pivotal trial of FICERA by the end of the year to enable interim analysis in mid-2027**
   **Initiation of alternate dose study expected in Q3 2026 to have results in time for potential U.S. accelerated approval**

4. **Exploring the EGFR x TGF-β biological fingerprint across additional solid tumors, including cSCC, anal canal and mCRC, to explore FICERA's pipeline in a product potential**

5. **Strong cash position of $539.8 million[2] expected to fund operations into 1H 2029**

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. Cash, cash equivalents and marketable securities as of March 31, 2026
DOR = duration of response; PFS = progression-free survival; OS = overall survival; mCRC = metastatic colorectal cancer; cSCC = cutaneous squamous cell carcinoma

# 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

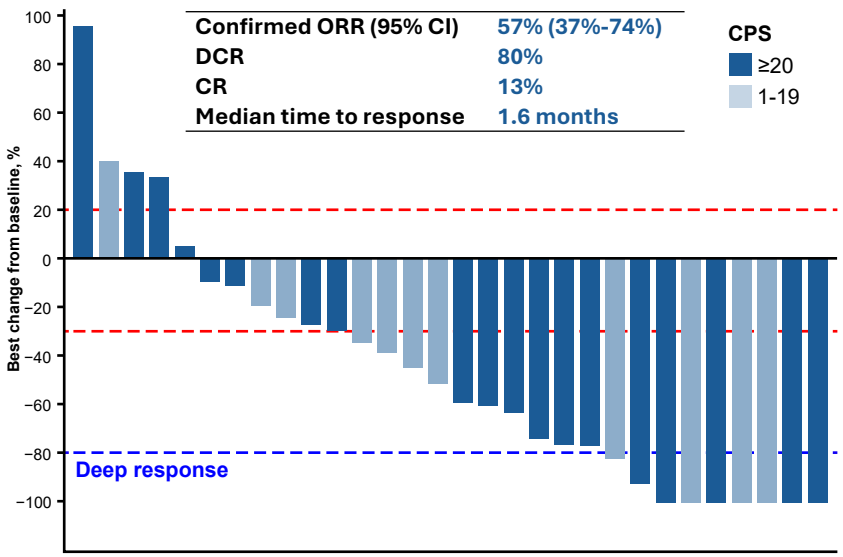
- Consistent safety, efficacy, **depth of response, and rapid time to response** supports further exploration for less frequent dosing schedule
- Data further **increase confidence in the pivotal study**

| | 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

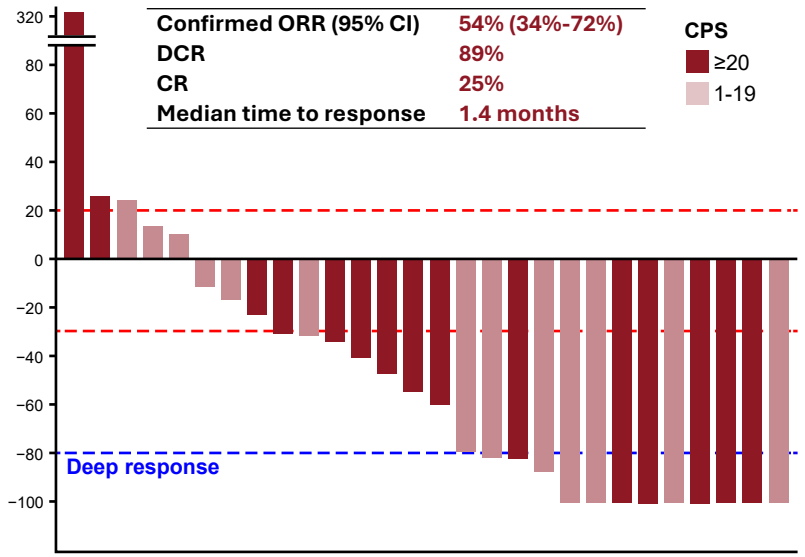
# TGF-β inhibition drives rapid, deep responses and dose-dependent CR rates across cohorts

## 750mg QW



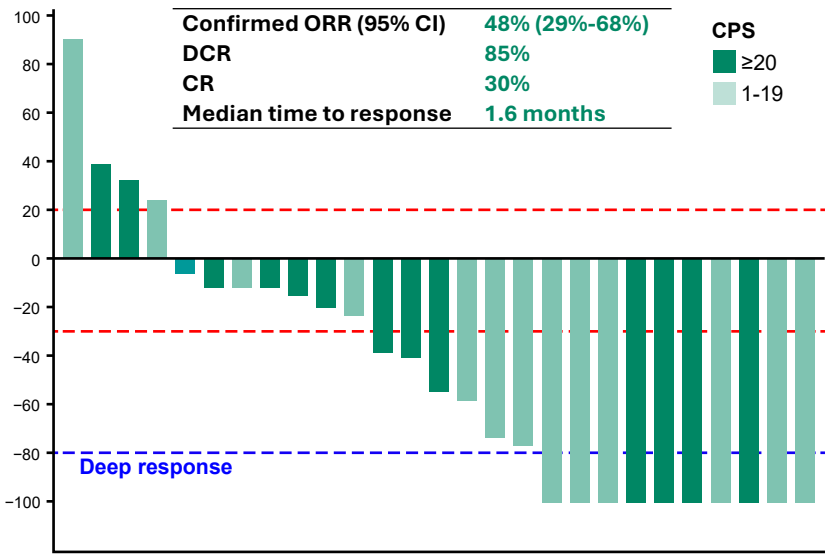

**Deep response: 47% (8/17)**

## 1500mg QW




**Deep response: 80% (12/15)**

## 2000mg Q2W



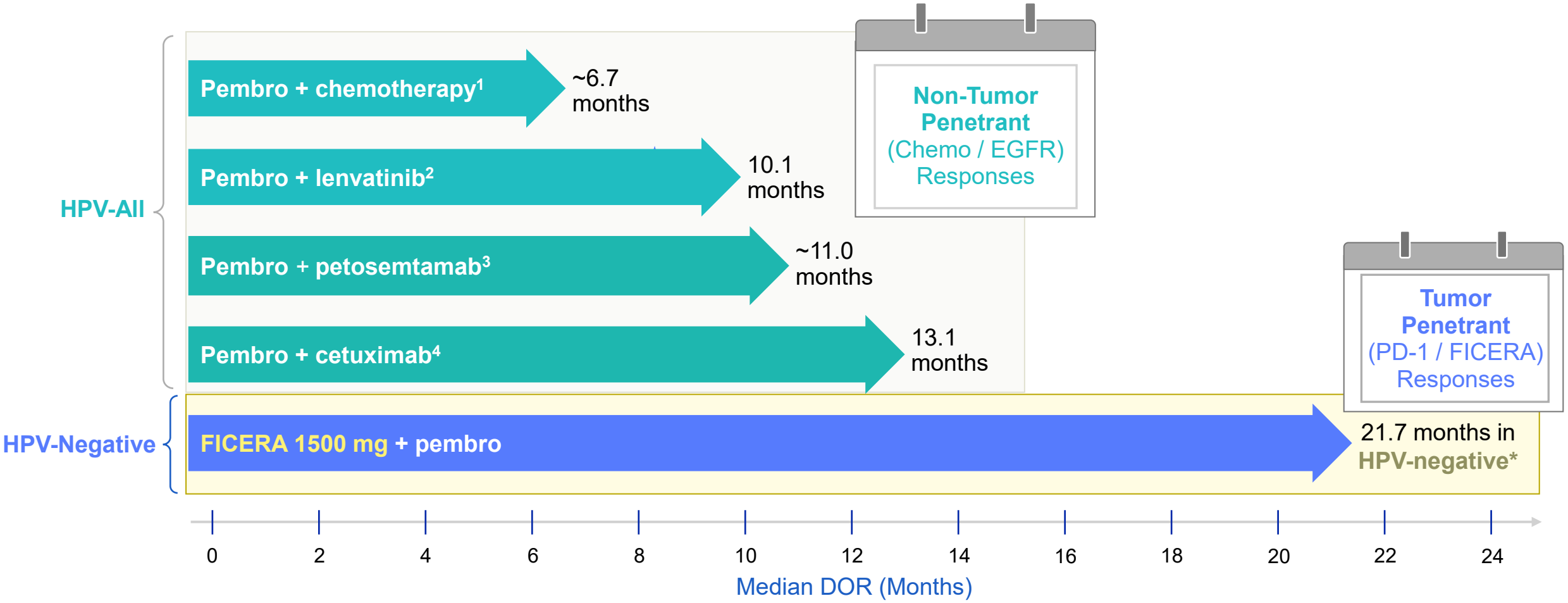

**Deep response: 77% (10/13)**

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

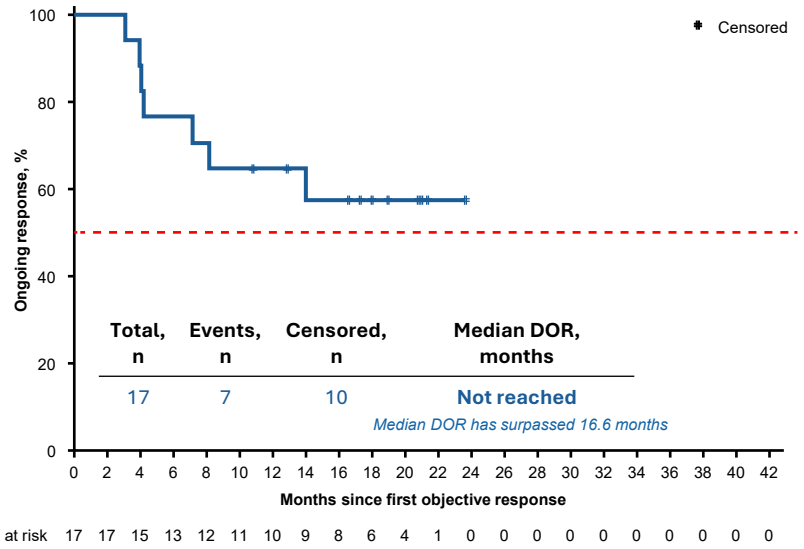





Based on historical published data. No head-to-head studies have been conducted, and cross-trial comparisons may not be reliable due to differences in molecule composition, trial design, and patient population and characteristics. Sources: 1. KEYNOTE-048: Burtness, Barbara, et al. The Lancet 394.10212 (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

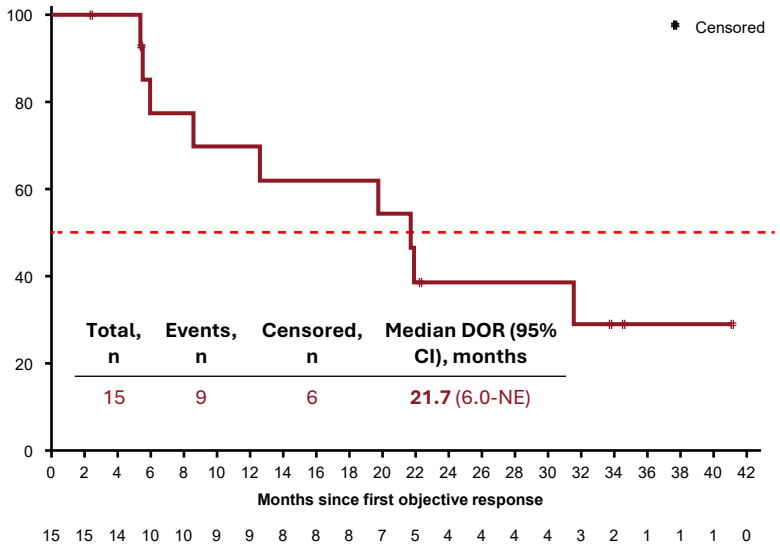
# FICERA demonstrated clinically meaningful DOR across dose cohorts

## 750mg QW



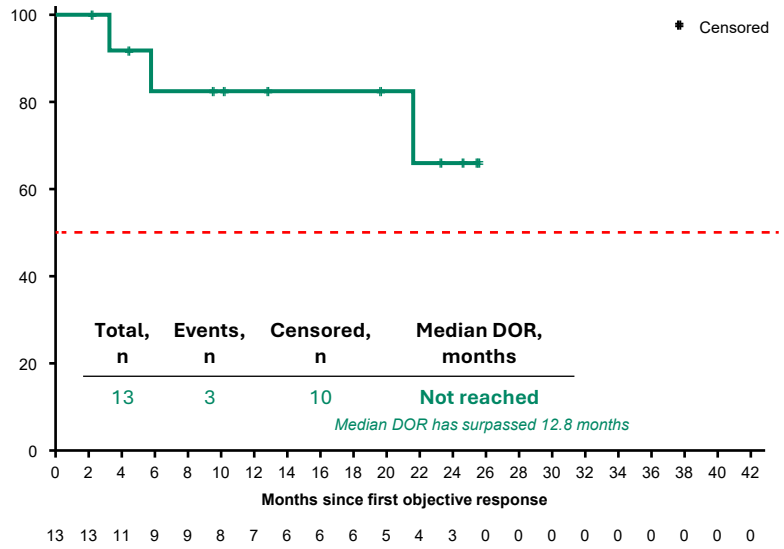

**Median DOR: not yet reached; has surpassed 16.6 months**

## 1500mg QW




**Median DOR: 21.7 months**

## 2000mg Q2W

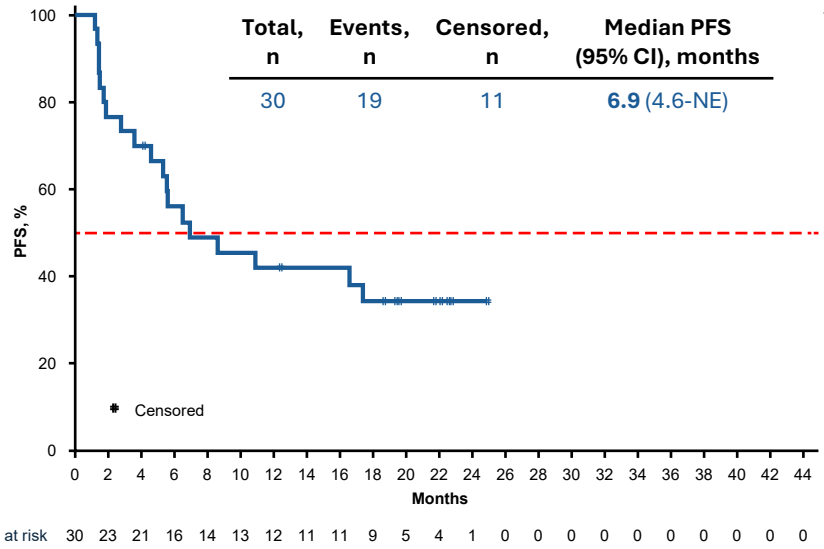



**Median DOR: not yet reached; has surpassed 12.8 months**

# FICERA demonstrated clinically meaningful PFS across dose cohorts

## 750mg QW

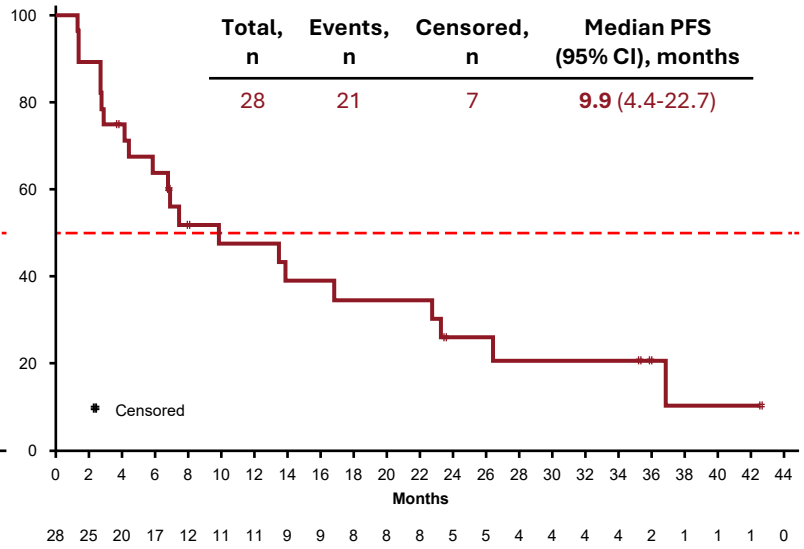
| Total, n | Events, n | Censored, n | Median PFS (95% CI), months |
|---|---|---|---|
| 30 | 19 | 11 | **6.9** (4.6-NE) |




**Median PFS: 6.9 months**

## 1500mg QW

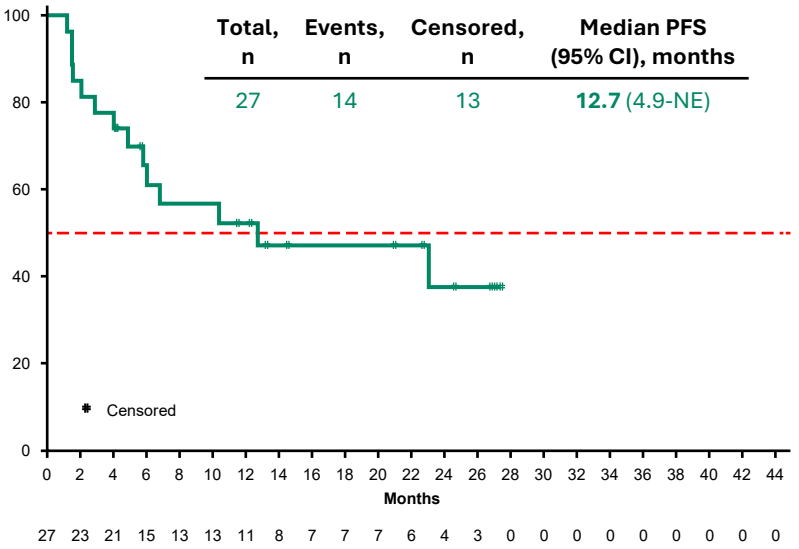
| Total, n | Events, n | Censored, n | Median PFS (95% CI), months |
|---|---|---|---|
| 28 | 21 | 7 | **9.9** (4.4-22.7) |




**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**

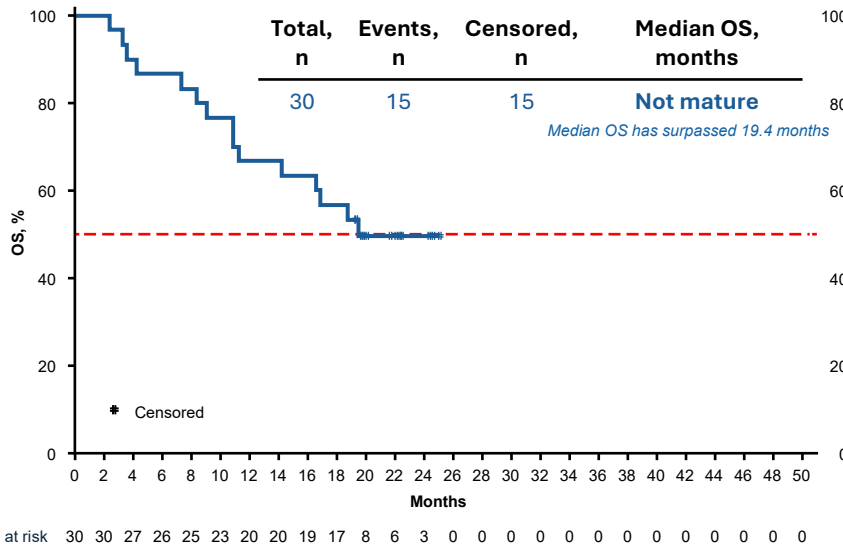
FICERA's median PFS of 9.9 months represents a **>3x increase** vs. pembrolizumab (~3.2 months[1])

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

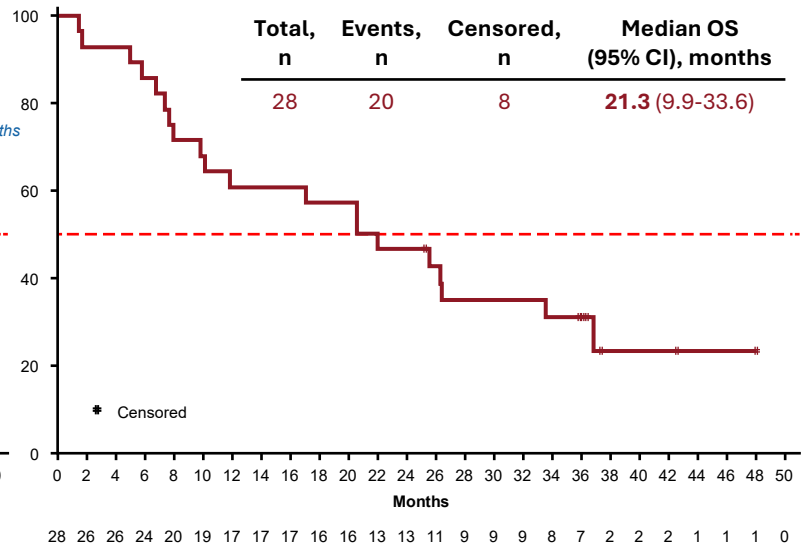
# FICERA demonstrated clinically meaningful OS across dose cohorts

## 750mg QW



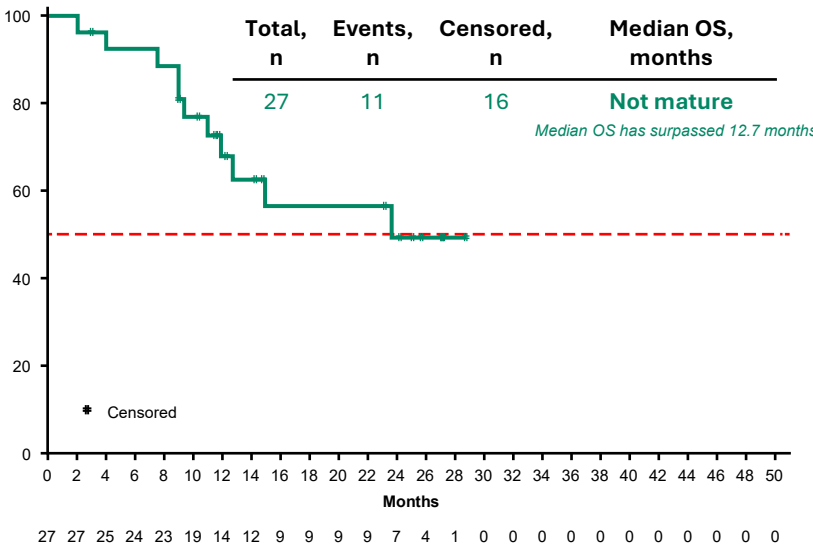

**Median OS: not yet mature; has surpassed 19.4 months**

## 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:**

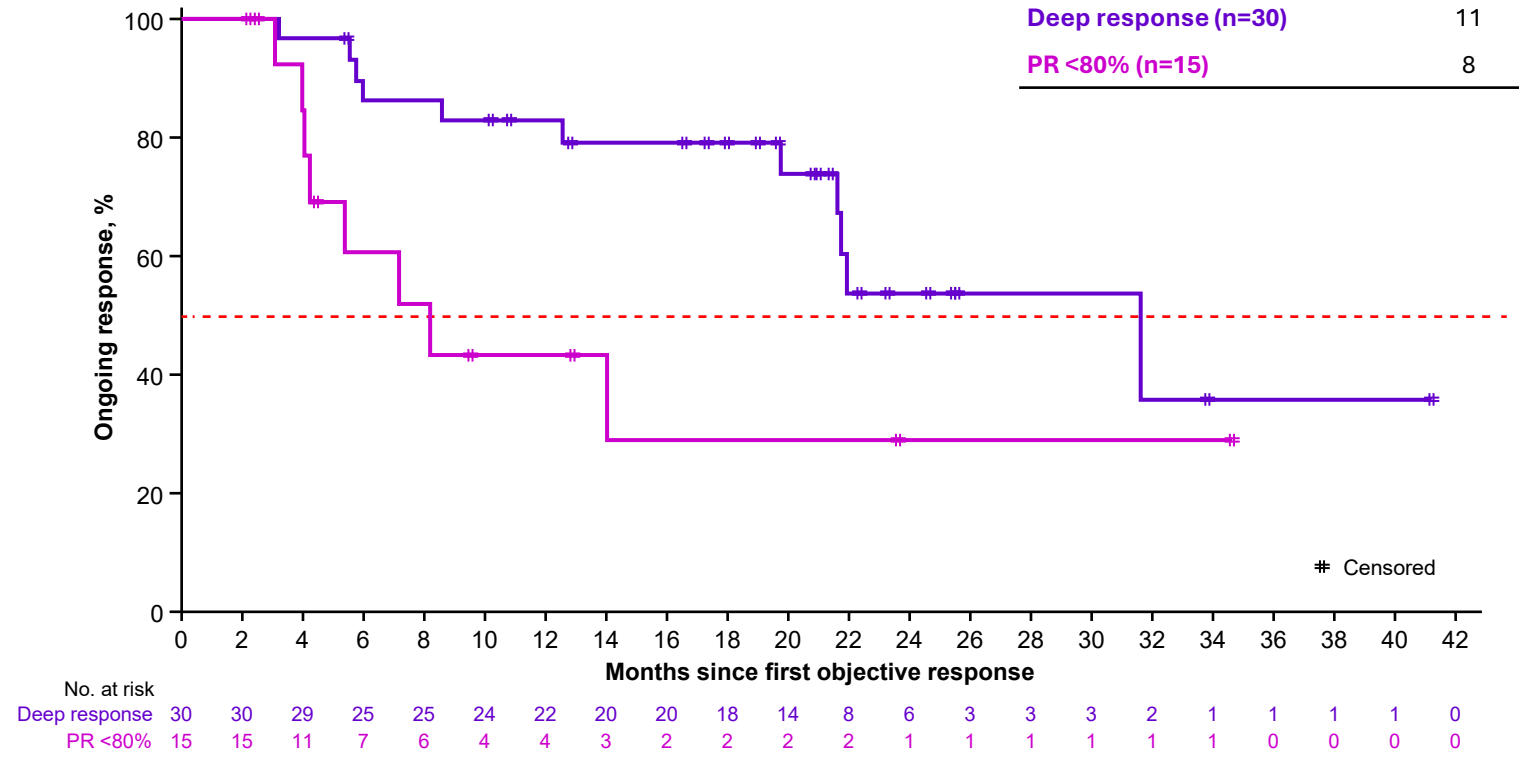
FICERA delivered 54-73% ORR, more than 3x pembrolizumab monotherapy (~15%)[1]

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) |

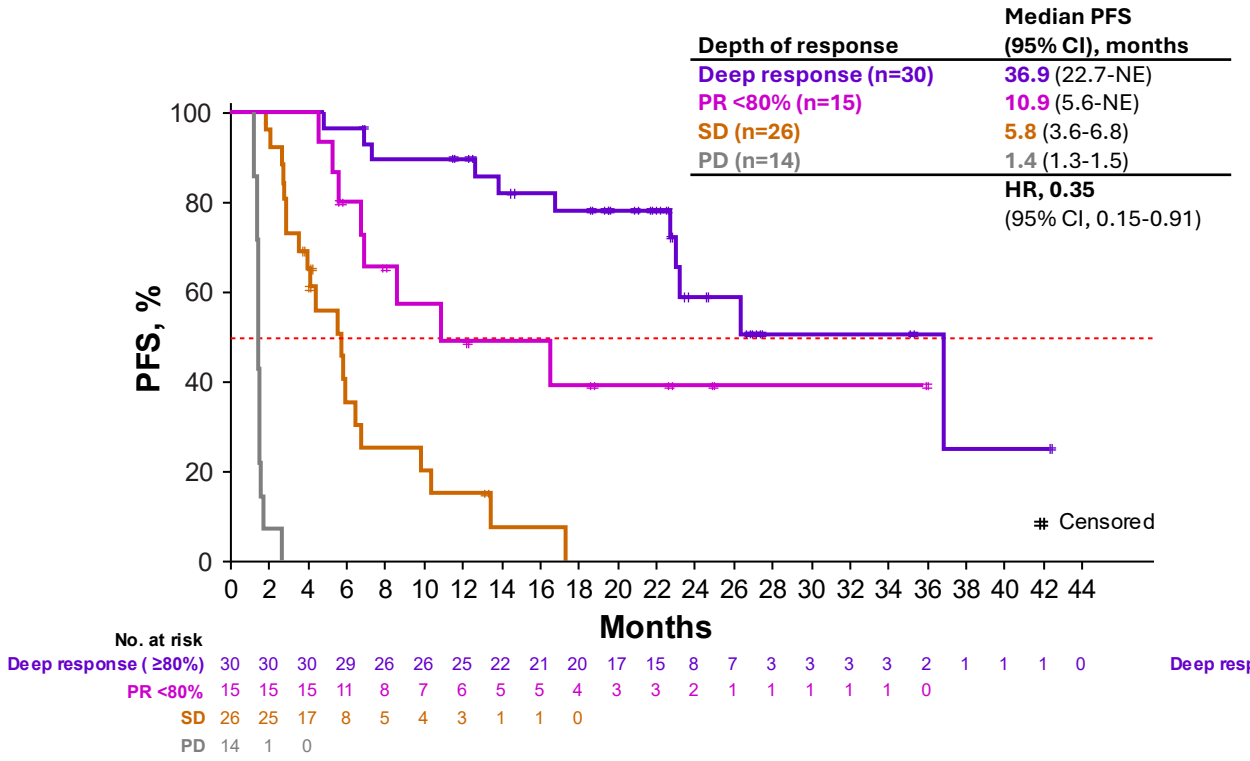



N=45 across 750mg, 1500mg, 2000mg dose cohorts

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

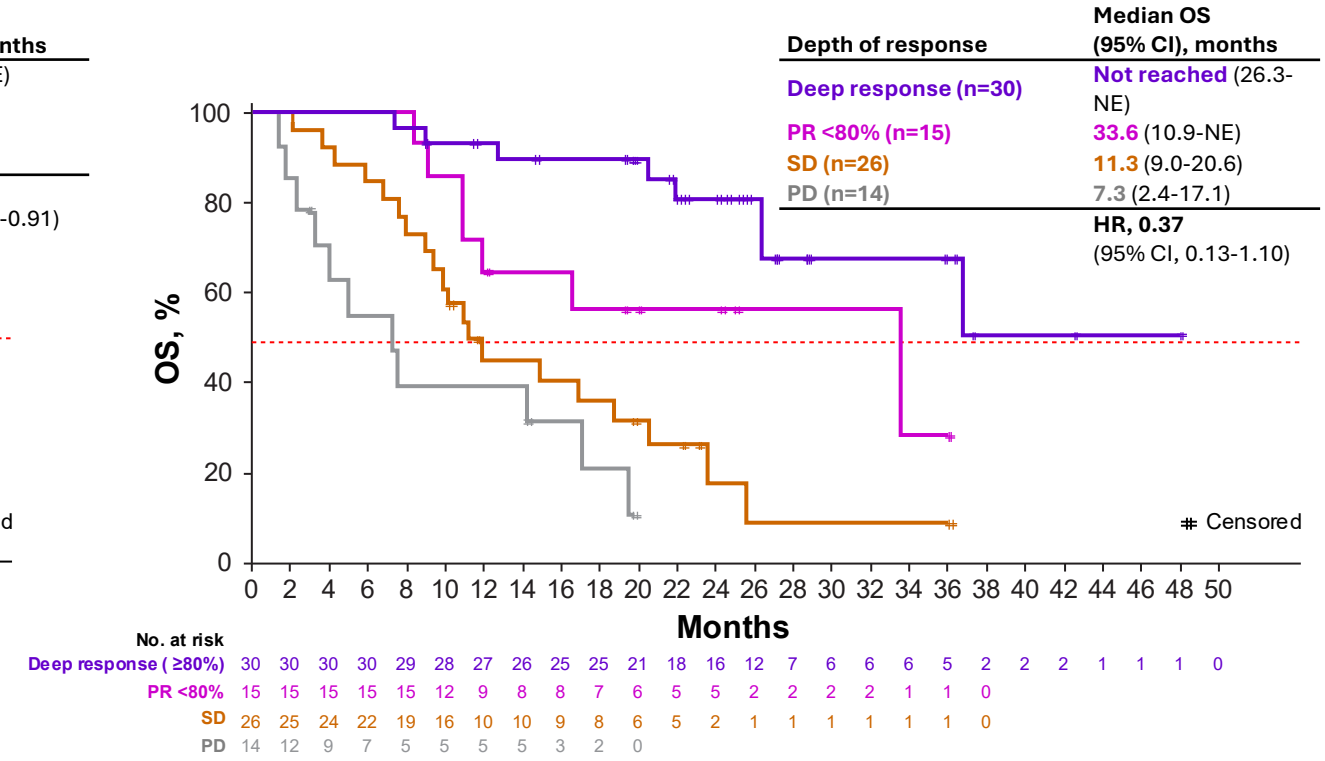
Data snapshot: March 31, 2026

# 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.

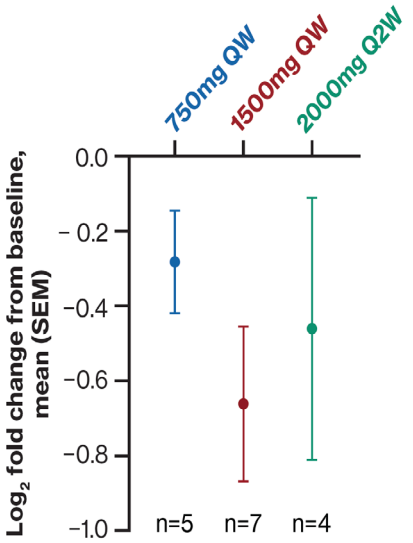
N=45 across 750mg, 1500mg, 2000mg dose cohorts

Data snapshot: March 31, 2026

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

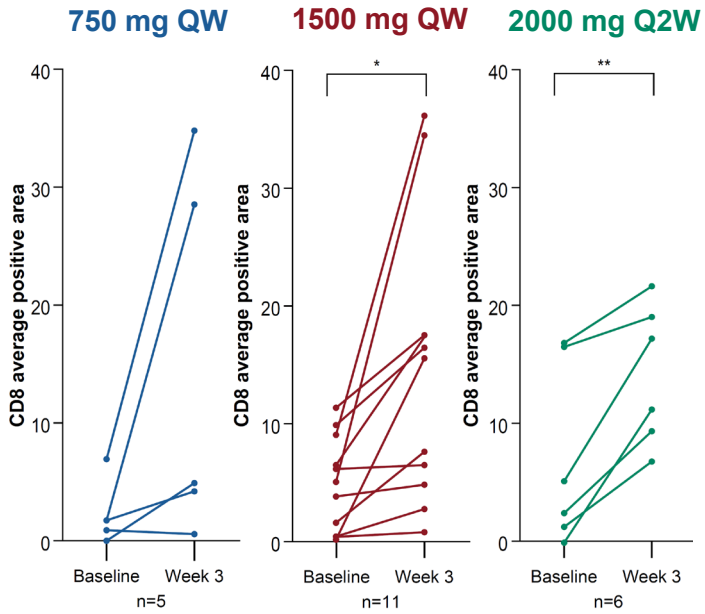
## TGF-β Inhibition

pSMAD2 ⬇




## Tumor Penetration

CD8+ T Cell Tumor Infiltration

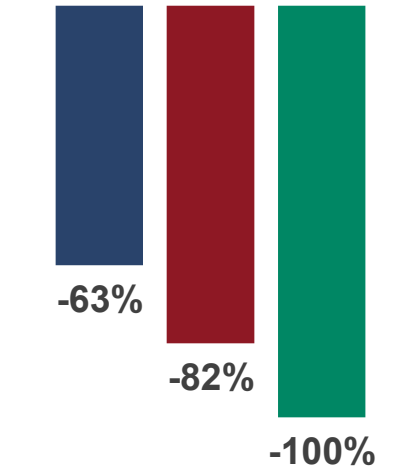



Plots show mean with SEM. Mann-Whitney Test from Log2 Baseline adjusted *p≤.05, **p ≤.01

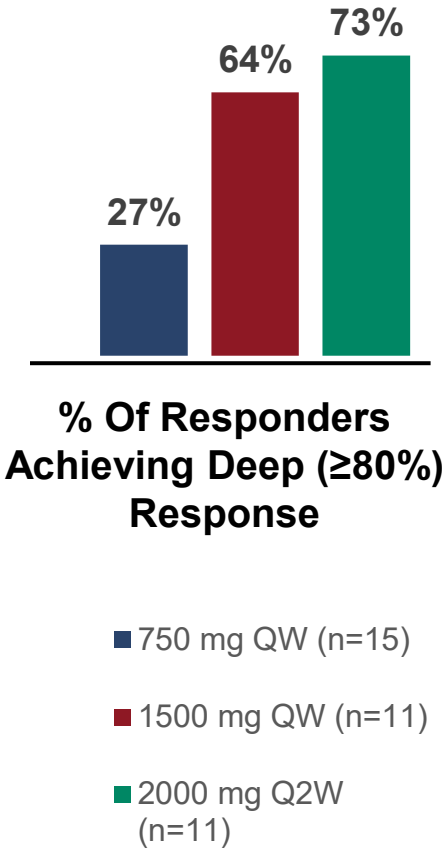
Increases in TGF-β inhibition directly in the TME enabled greater tumor penetration to **drive deeper and more durable responses**

## 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.

# FICERA case highlight: rapid lesion shrinkage and deep response in aggressive HNSCC

## 66-year-old male with recurrent oral cavity cancer

**Disease characteristics**

- Oral Cavity
- LR only
- CPS 20

**Multiple Comorbidities**

**ECOG 1 Performance Status**

### Prior Therapy:

• **Oct 2021:** Partial glossectomy + (L) neck dissection

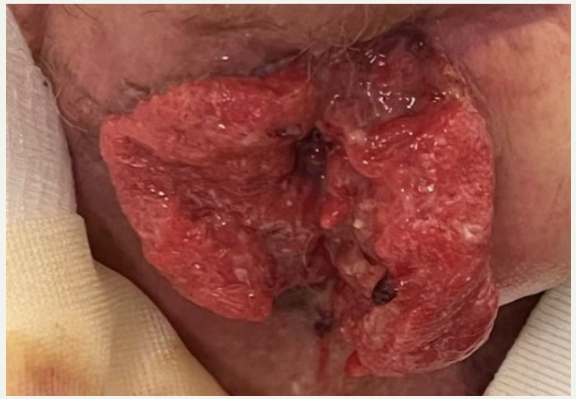
• **Jun–Aug 2023:** (L) neck recurrence → chemoradiation

• **Dec 2023:** (L) neck recurrence → (L) radical neck dissection

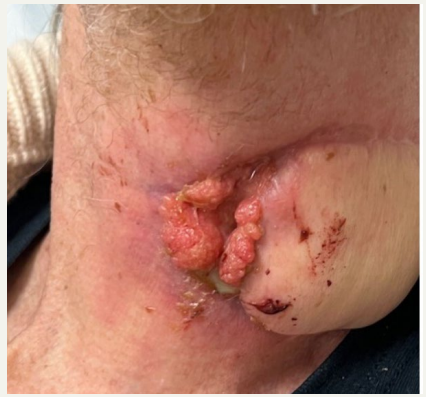
### Study Therapy:

• **May 2024 – Jan 2025:** FICERA 750 mg QW + pembrolizumab

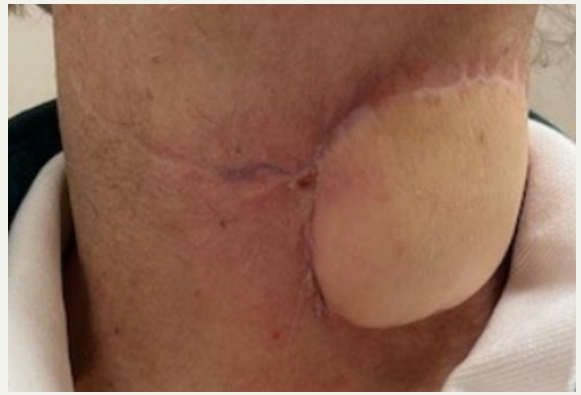
**Tumor assessment**
**Baseline:** One target lesion of 49 mm
**6-week scan:** 55% shrinkage in target lesion
**Survival**: Patient is in survival follow up- and alive as of last contact date of December 2025.



Baseline



Two Weeks



Eight Weeks

# 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

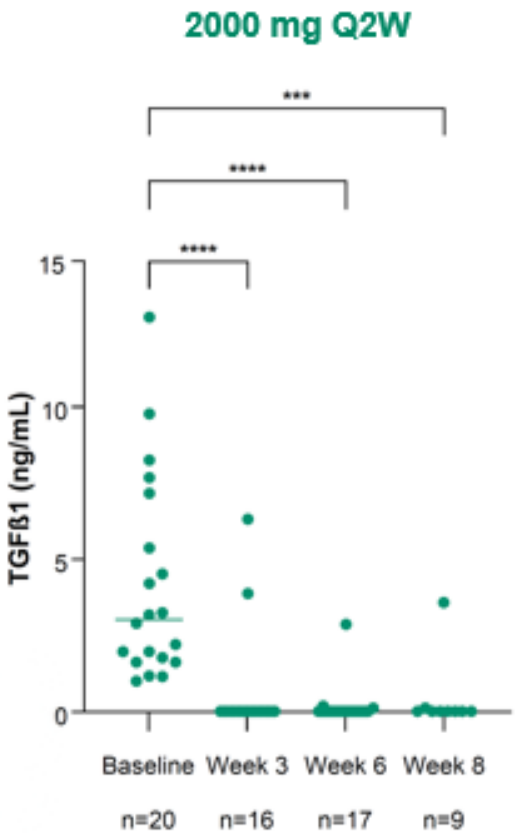
**Rapid and deep responses** that yield **durability and long-term outcomes** due to TGF-β inhibition

## 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

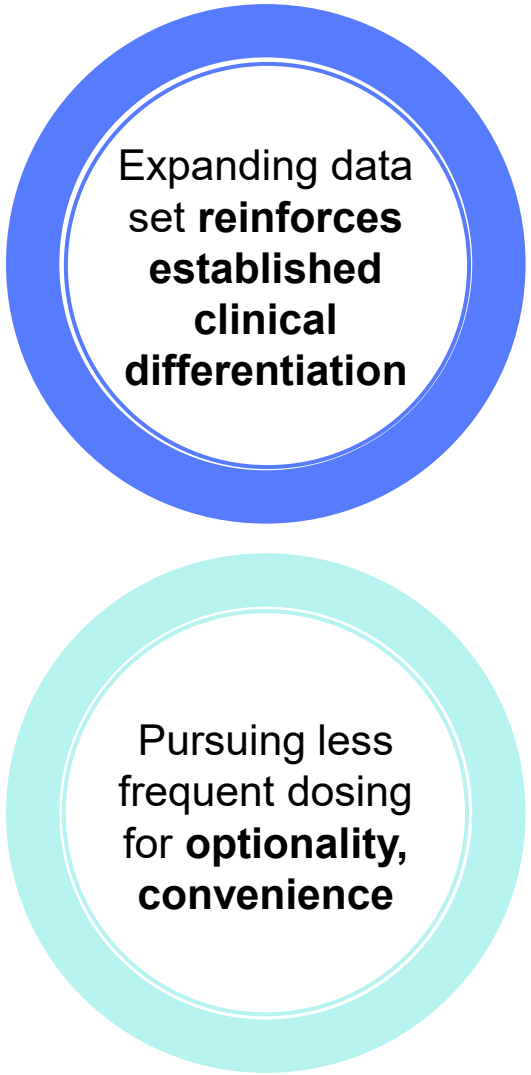
## Advancing an Alternate Dosing Regimen Strategy

Based on discussions with the FDA, expect to initiate an alternate dose study in Q3 2026 to evaluate FICERA + pembrolizumab in 1L R/M HPV-negative HNSCC, to have results in time for potential U.S. accelerated approval



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)**

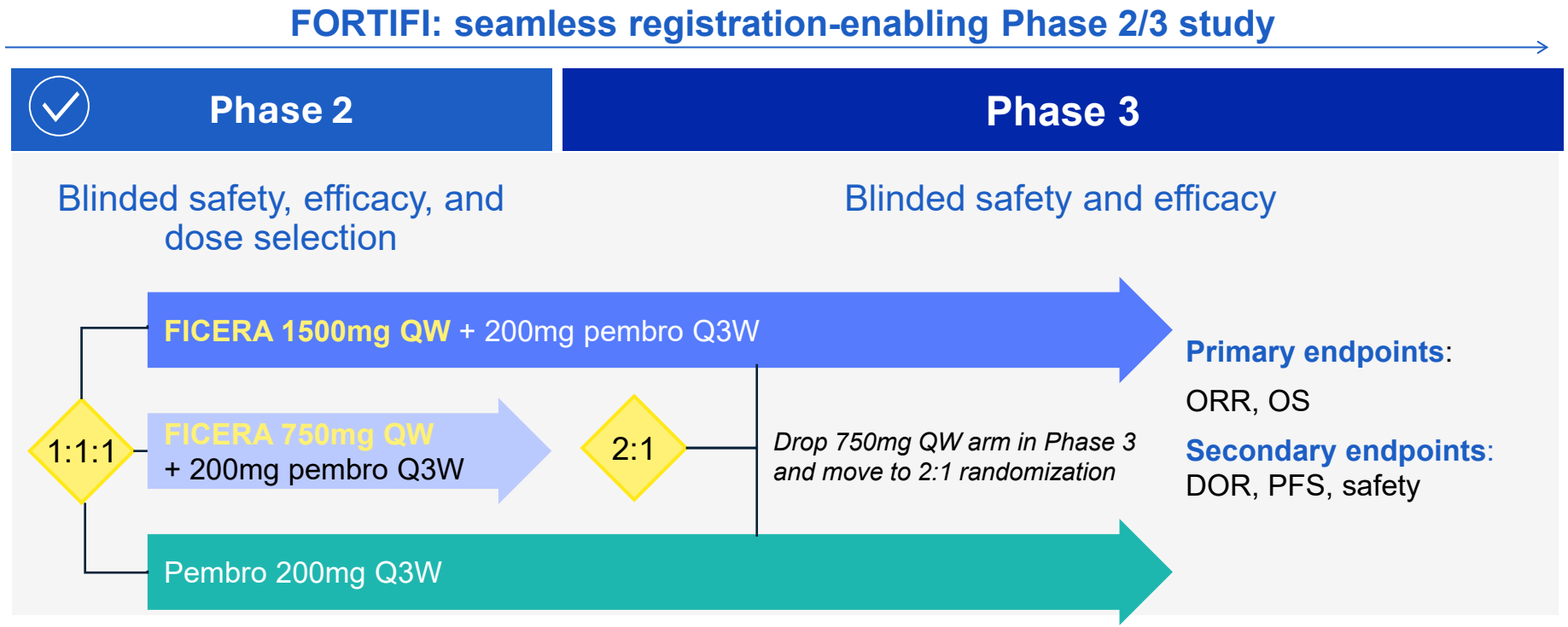
**Deep responses translate into durable long-term outcomes across DOR, PFS, and OS**

**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



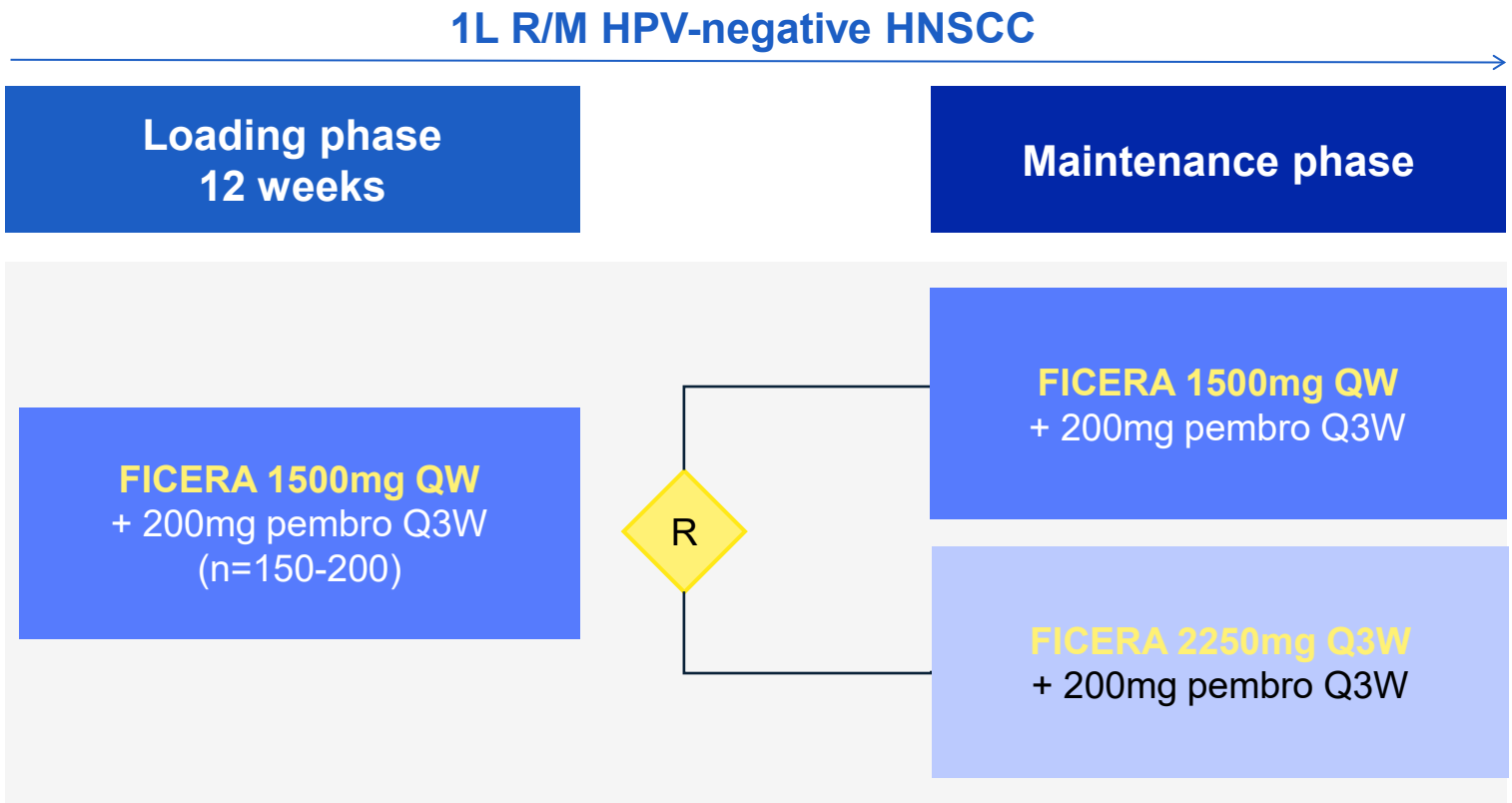

## Phase 3 initiated and currently enrolling with 1500mg QW FICERA

- 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

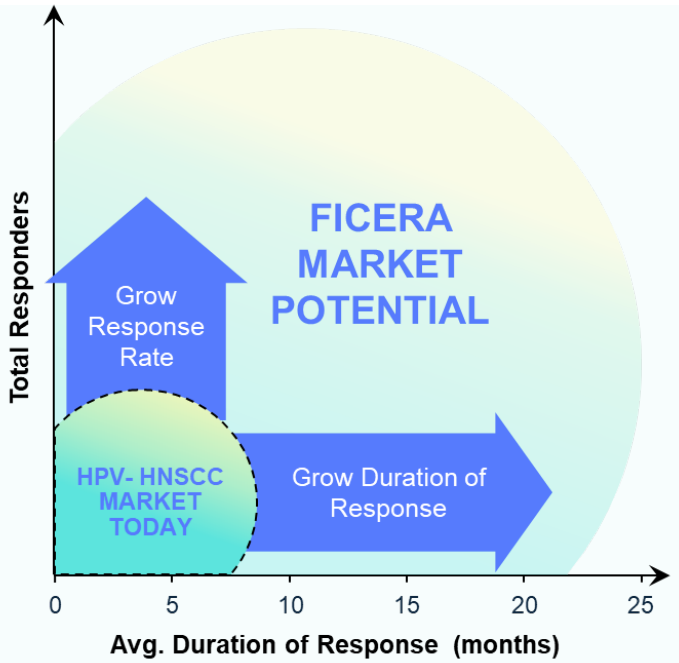
**Plan to initiate study in Q3 2026 to have results in time for potential U.S. accelerated approval**



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

# Preparing for Commercial Success

# FICERA has the potential to significantly expand the HPV-negative HNSCC market




## Large & Growing Patient Population

With ~50K HPV-negative HNSCC patients annually incident in the US, EU5, and Japan[2]

**$5B+**

projected global market for HNSCC by 2030[1]

## Pioneer Treatment Paradigm Shift

Continue to build market understanding of HPV-negative HNSCC as a distinct clinical disease

## Drive Better Patient Outcomes

2-3X responses
2-3X duration of response
2X survival

## Expand The Market

>2X potential growth in patient months
Additional opportunities to further grow the market (e.g., CPS = 0, HPV-positive smokers)

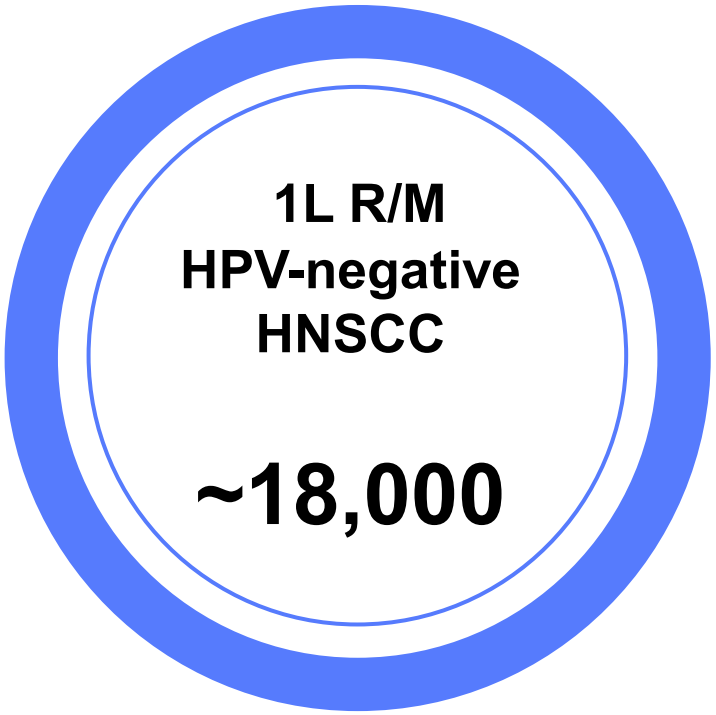


No head-to-head studies have been conducted, and cross-trial comparisons may not be reliable due to differences in molecule composition, trial design, and patient population and characteristics.
1. Tessellon patient flow modeling; SEER; country specific registries; literature review; 2. Evaluate Pharma 2025

# 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

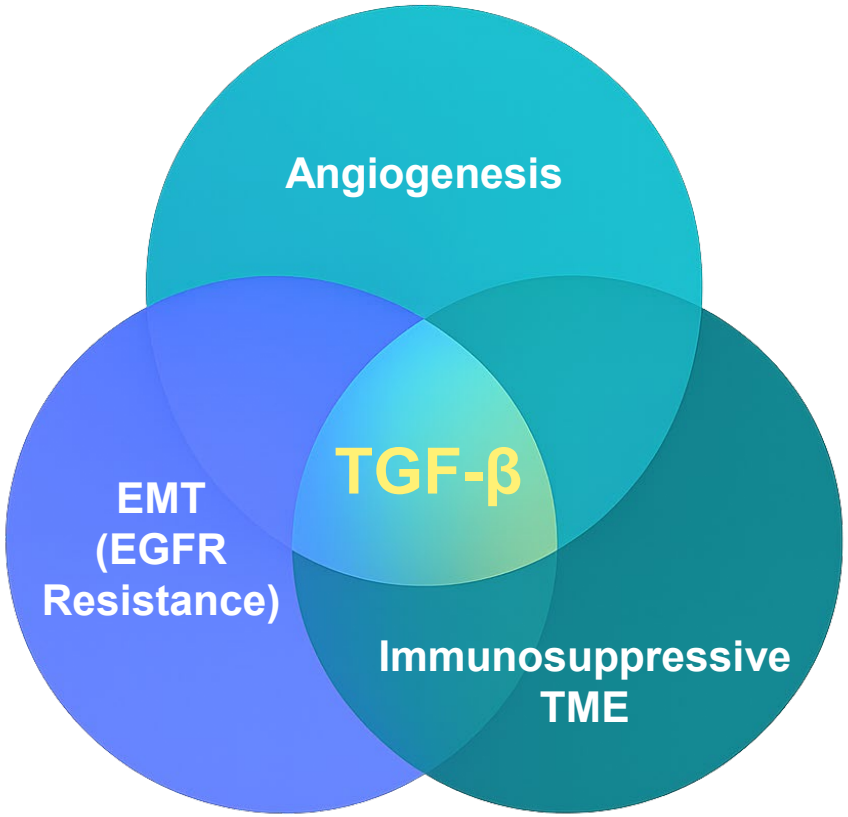
R/M subsegment



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

# TGF-β is heavily implicated in CRC metastasis and resistance to treatment

## Key Drivers of Metastatic CRC




**TGF-β is highly expressed in CRC and drives metastasis via:**

- **EMT**: Tumor cells undergo the epithelial-mesenchymal transition (EMT) process and then spread to distant sites
- **Angiogenesis**: TGF-β signaling mediates the formation of new blood vessels, which promotes intravasation of tumor cells
- **Immunosuppression**: TGF-β signaling from immune cells such as CAFs and TAMs contribute to an immunosuppressive TME

**FICERA combines two historical mechanisms for treating mCRC, simultaneously targeting both anti-EGFR and anti-angiogenic pathways via TGF-β inhibition**



CAF, cancer-associated fibroblast; TAM, tumor-associated macrophage; TME, tumor microenvironment

# FICERA positioned to address multiple pathways in mCRC

## Currently, two main targeted approaches to treating RAS/BRAFwt mCRC (MSS):

### Anti-EGFR

**Approved Agents:**
- Cetuximab★
- Panitumumab★

**In Development**
- Amivantamab (EGFR x MET)
- Petosemtamab (EGFR x LGR5)

★ Standard of care agents

### FICERA

**Simultaneously targeting both anti-EGFR and anti-angiogenic pathways via TGF-β inhibition**

Potential to address both left-sided and right-sided mCRC in 1L

*Combat resistance mechanisms to drive durability and PFS*

### Anti-Angiogenic / Anti-VEGF

**Approved Agents:**
- Bevacizumab★
- Fruquintinib
- Regorafenib

**In Development**
- Zanzalintinib (multi TKI)
- INCA33890 (PD-1 x TGF-βR2)

# 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]

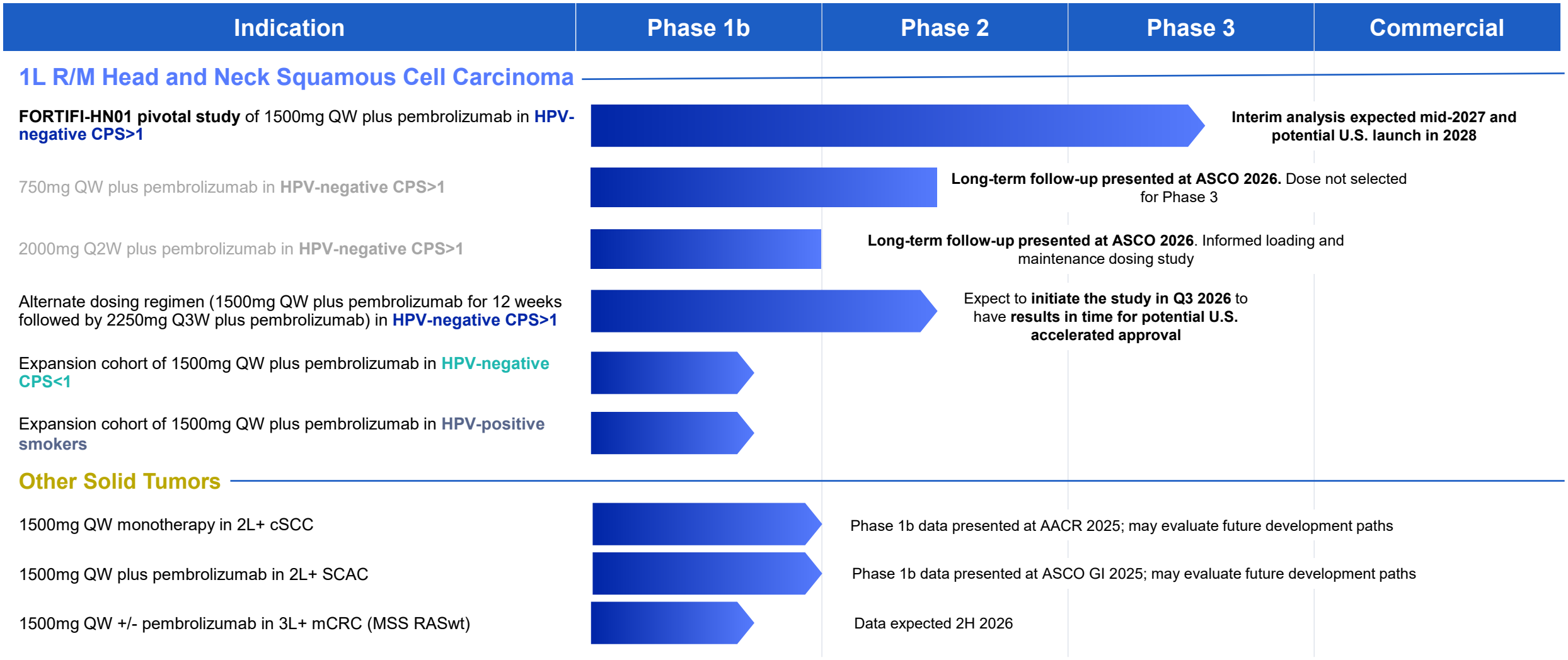


1. Prager, et al. New England Journal of Medicine (2023).
2. Mayer, et al. New England Journal of Medicine (2015).
3. Dasari, et al. The Lancet (2023).

# Anticipated key milestones in 2026 to drive growth and value inflection

| 2026 Milestones | Timing |
|---|---|
| Determine OBD for Phase 2/3 FORTIFI-HN01 study of ficerafusp alfa in 1L R/M HPV-negative HNSCC | ✓ |
| Present data from an exploratory Phase 1b expansion cohort evaluating 2000 mg of ficerafusp alfa every other week in combination with pembrolizumab in 1L HPV-negative R/M HNSCC patients | ✓ |
| Hired a CCO to advance organizational preparation for launch readiness | ✓ |
| Present long-term follow-up data from Phase 1b study of ficerafusp alfa in combination with pembrolizumab in 1L R/M HPV-negative HNSCC | ✓ |
| Initiate an alternate dose study in Q3 2026 to evaluate FICERA + pembrolizumab in 1L R/M HPV-negative HNSCC, to have results in time for potential U.S. approval | Q3 2026 |
| Present data from Phase 1b expansion cohort evaluating ficerafusp alfa both as monotherapy and in combination with pembrolizumab in patients with 3L+ metastatic CRC (RAS/BRAF wild type MSS) | 2H 2026 |
| Achieve substantial enrollment in FORTIFI-HN01 pivotal study to enable interim analysis in mid-2027 | Q4 2026 |

# Maximizing the franchise value of FICERA



BICARA THERAPEUTICS™

# Thank You