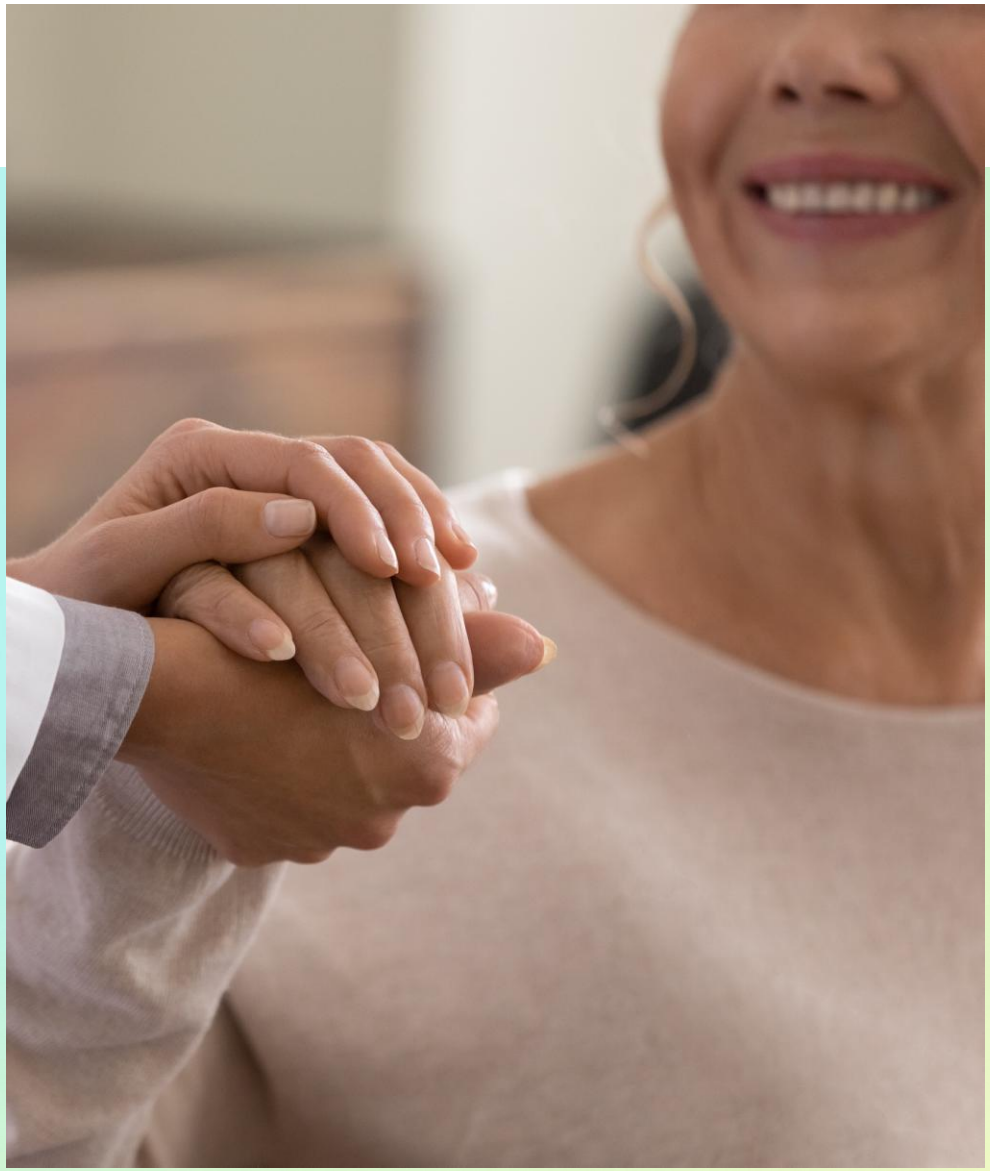
BICARA THERAPEUTICS™

ASCO 2025 Clinical Update

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



June 2025

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 statements regarding our clinical development of ficerafusp alfa in combination with pembrolizumab and presentation of updated results from an open-label, multicenter Phase 1/1b trial of ficerafusp alfa with pembrolizumab in patients with recurrent or metastatic head and neck squamous cell carcinoma, and the expected therapeutic potential and ability, profile and clinical benefits of ficerafusp alfa, including potential and anticipated efficacy, depth, durability, tolerability, and success, and the potential clinical results from the Phase 2/3 pivotal trial of ficerafusp alfa. 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, as well as the potential contribution of our employees and board to our growth and success as a Company; 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-recently filed Quarterly Report 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.

Agenda & Today's Presenters

1. **Ficerafusp Alfa (FICERA) Overview**
   Mechanism of Action & AACR 2025 Data Summary

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

2. **ASCO 2025 Clinical Update**
   1L R/M HNSCC – Ph. 1/1b Clinical Data (**HPV-Neg**)

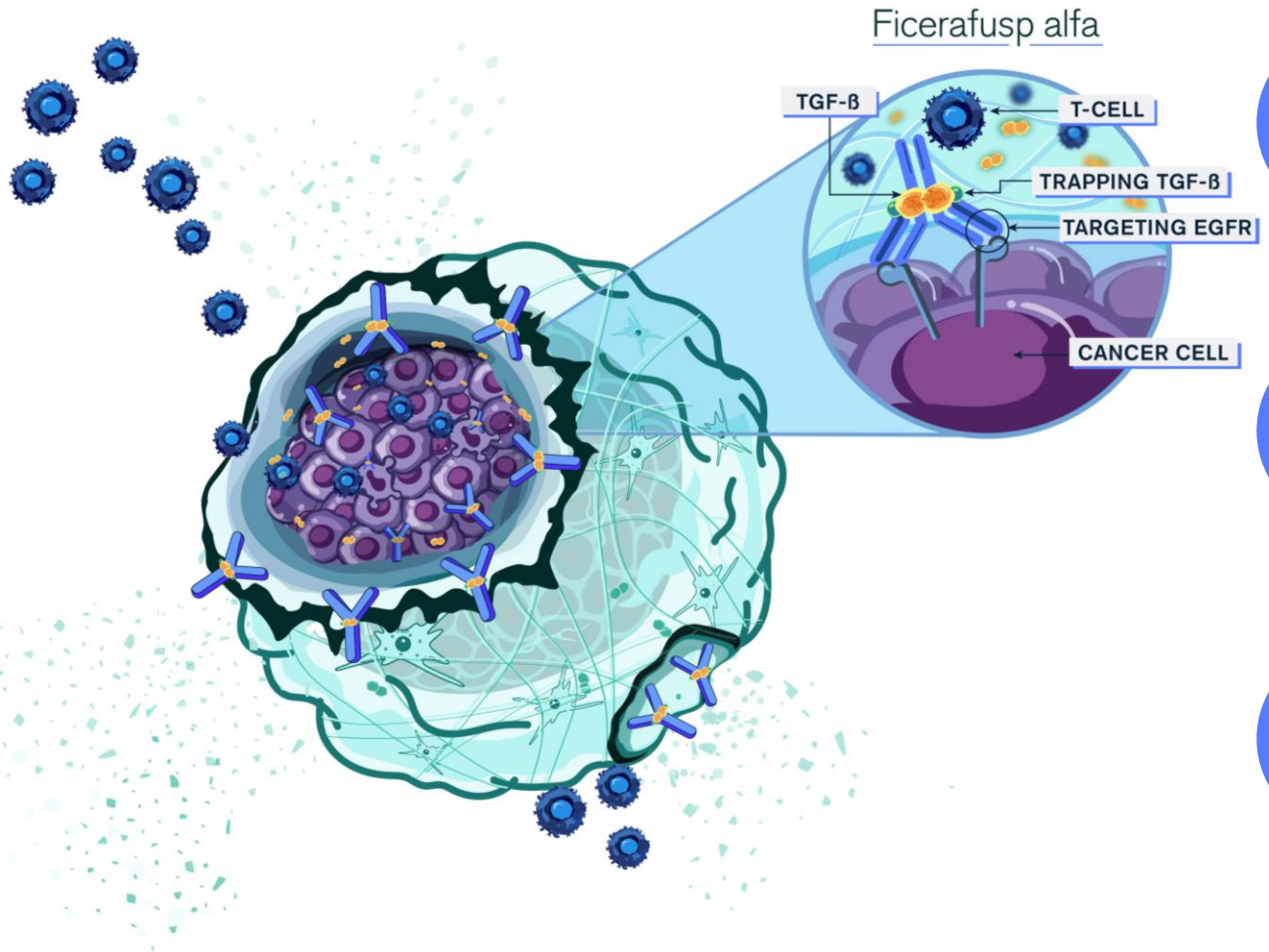
David Raben, M.D.
Chief Medical Officer

3. **FORTIFI-HN01 Ph. 2/3 Trial**
   Trial Overview

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

AACR = American Association for Cancer Research; R/M = recurrent / metastatic; HNSCC = head and neck squamous cell carcinoma; HPV = human papilloma virus; HPV-neg = HPV-negative.

Ficerafusp alfa (FICERA) was designed to tackle a major challenge in solid tumor cancers: tumor penetration



1. Inadequate tumor penetration has challenged the treatment of many solid tumor cancers including R/M HNSCC

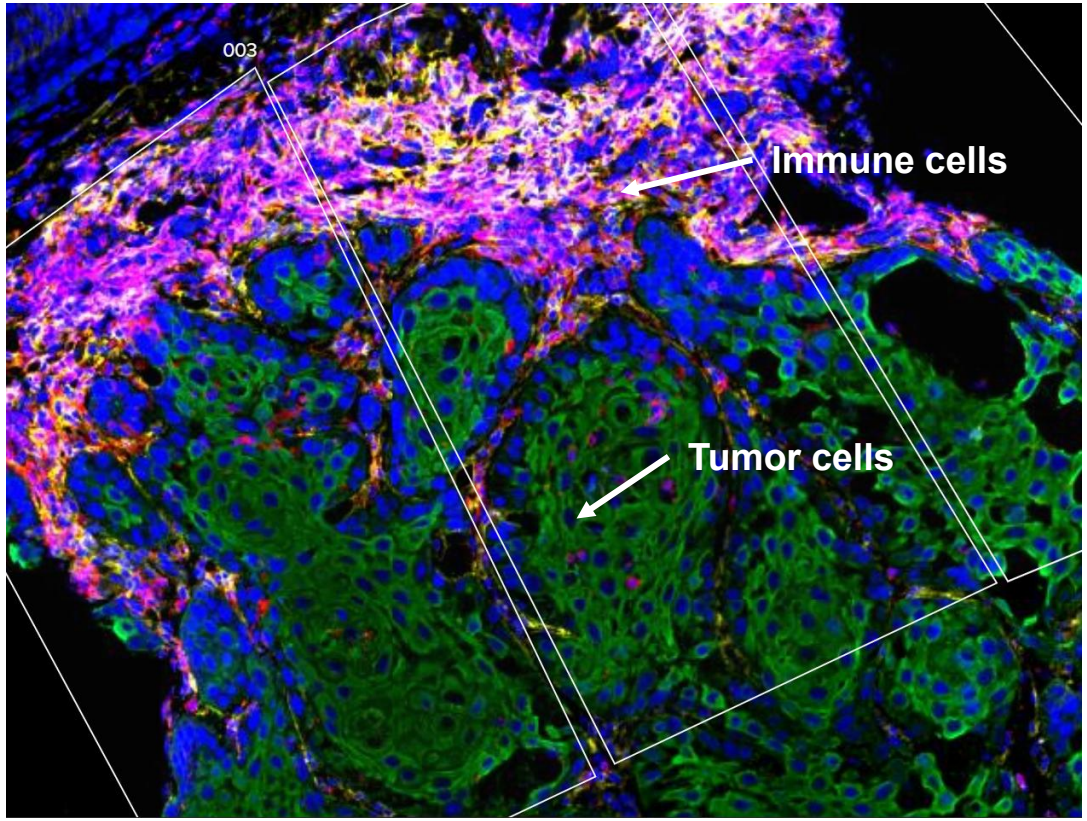
2. FICERA was specifically designed to enable tumor penetration by breaking barriers in the tumor microenvironment

3. FICERA's tumor penetration drives deep and durable responses

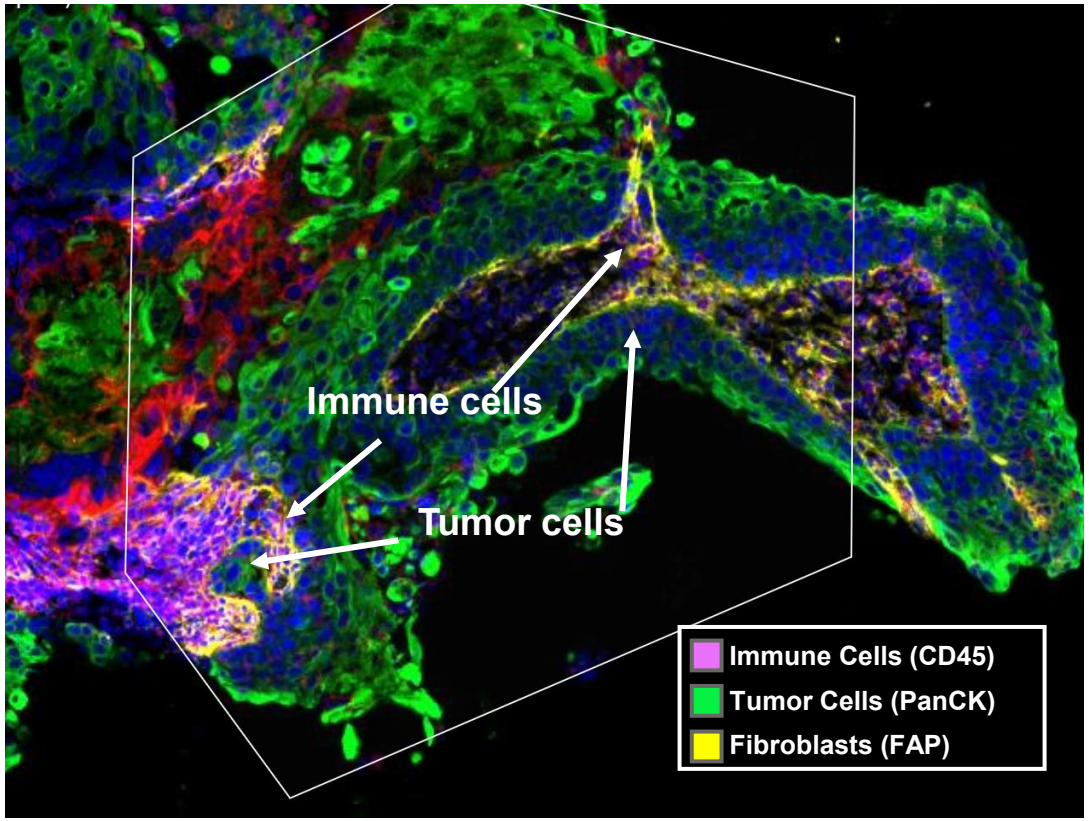
MOA

FICERA was designed to enable tumor penetration by breaking barriers in the tumor microenvironment (TME)

Baseline



FICERA + Pembro (3wks)



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

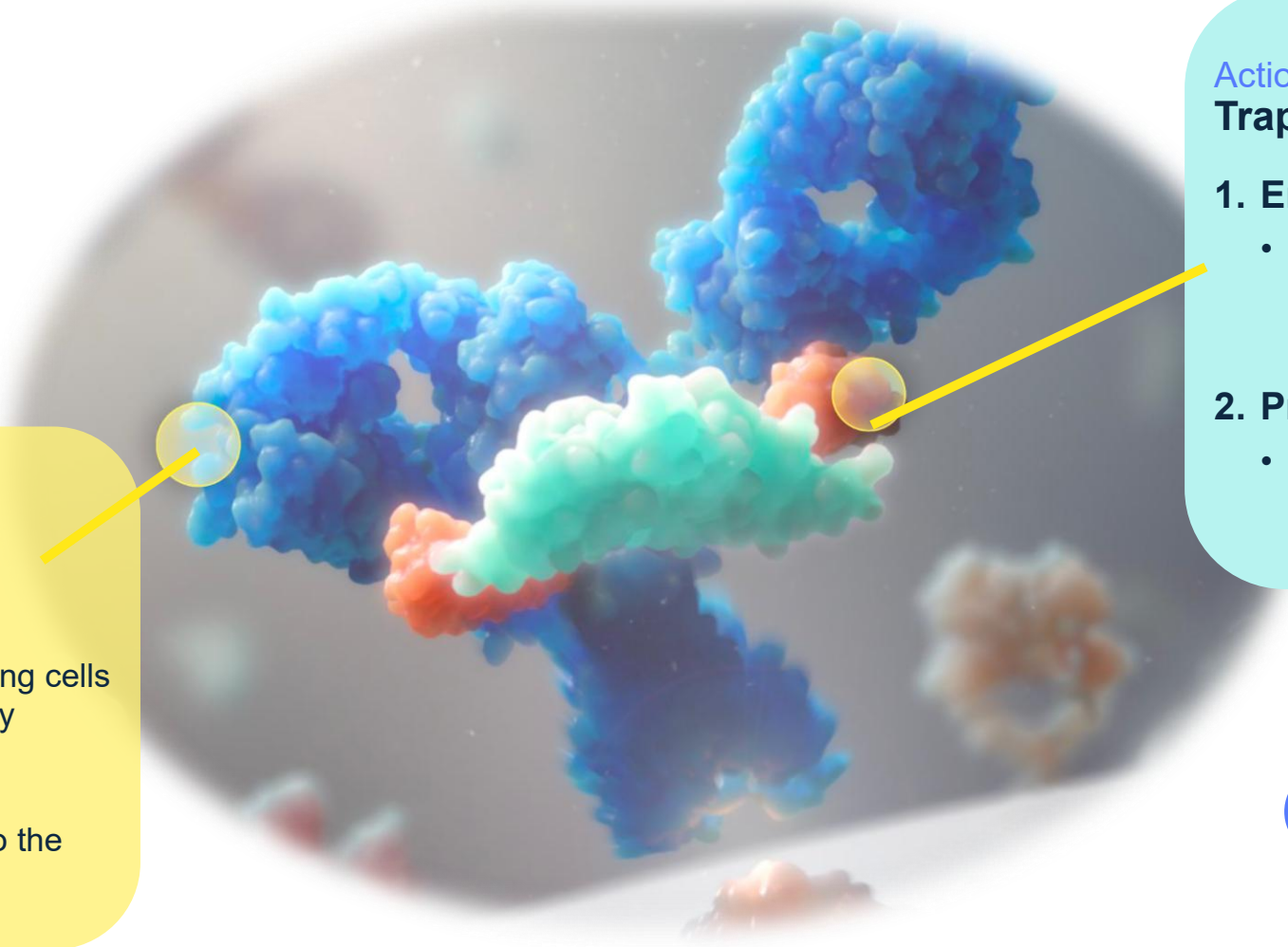
MOA = mechanism of action; TME = tumor microenvironment; PR = partial response

MOA

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

Designed to:

- Improve tolerability
- Improve anti-tumor activity



Action 1

Targeting EGFR

1. **Direct anti-tumor effect**
   - Inhibits EGFR signaling, killing cells
   - Maintains ADCC functionality
2. **Drives tumor targeting**
   - Localizes TGF-β inhibition to the TME

Action 2

Trapping TGF-β

1. **Enables tumor penetration**
   - Breaks the barriers in the TME by reducing fibrosis and T-cell exclusion / suppression
2. **Prevents resistance**
   - Prevents known EGFR resistance mechanism (via EMT)

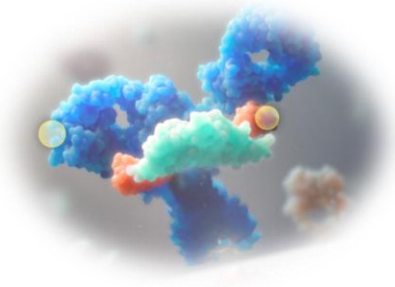
Goal:

- Increase depth and duration of response

EGFR = epidermal growth factor receptor; TGF = transforming growth factor; ADCC = antibody dependent cell-mediated cytotoxicity, TME = tumor microenvironment, EMT = epithelial-mesenchymal transition.

MOA

FICERA tumor penetration via reduced EMT in HPV-Neg HNSCC



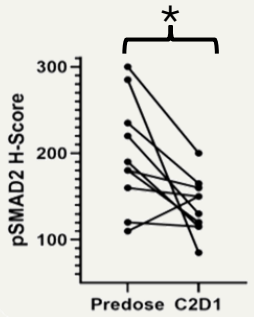
1 Inhibiting EGFR & TGF-β

2 Increasing Immune Activation / Penetration

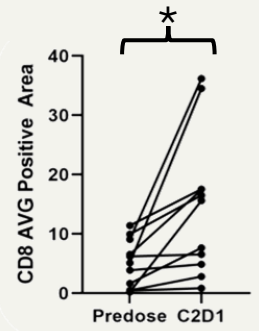
3 Reducing EMT Resistance

HPV-Neg Paired Biopsies[1] Illustrate FICERA MOA

TGF-β Inhibition



CD8+ T-Cells



Paired Biopsy Spatial Transcriptomics

(FICERA + pembro)

Reduced EMT →

EGFR Inhibition →

TGF-β Inhibition →

Down-Regulated in Tumor

HALLMARK PATHWAY	Gene Set (n)	NES	p.adj
EPITHELIAL_MESENCHYMAL_TRANSITI	189	-3.43	8.96E-34
HYPOXIA	177	-3.00	7.71E-20
APICAL_JUNCTION	169	-2.66	9.23E-13
TNFA_SIGNALING_VIA_NFKB	189	-2.58	9.23E-13
GLYCOLYSIS	175	-2.50	2.07E-11
G2M_CHECKPOINT	185	-2.29	7.17E-09
CHOLESTEROL_HOMEOSTASIS	67	-2.25	1.27E-05
ESTROGEN_RESPONSE_LATE	170	-2.23	1.24E-07
P53_PATHWAY	186	-2.16	5.54E-08
MYOGENESIS	148	-2.16	1.24E-06
COAGULATION	102	-2.13	1.71E-05
MTORC1_SIGNALING	183	-2.06	1.62E-06
ANGIOGENESIS	33	-2.06	1.45E-03
TGF_BETA_SIGNALING	52	-2.04	3.66E-04

Increased Immune Activation →

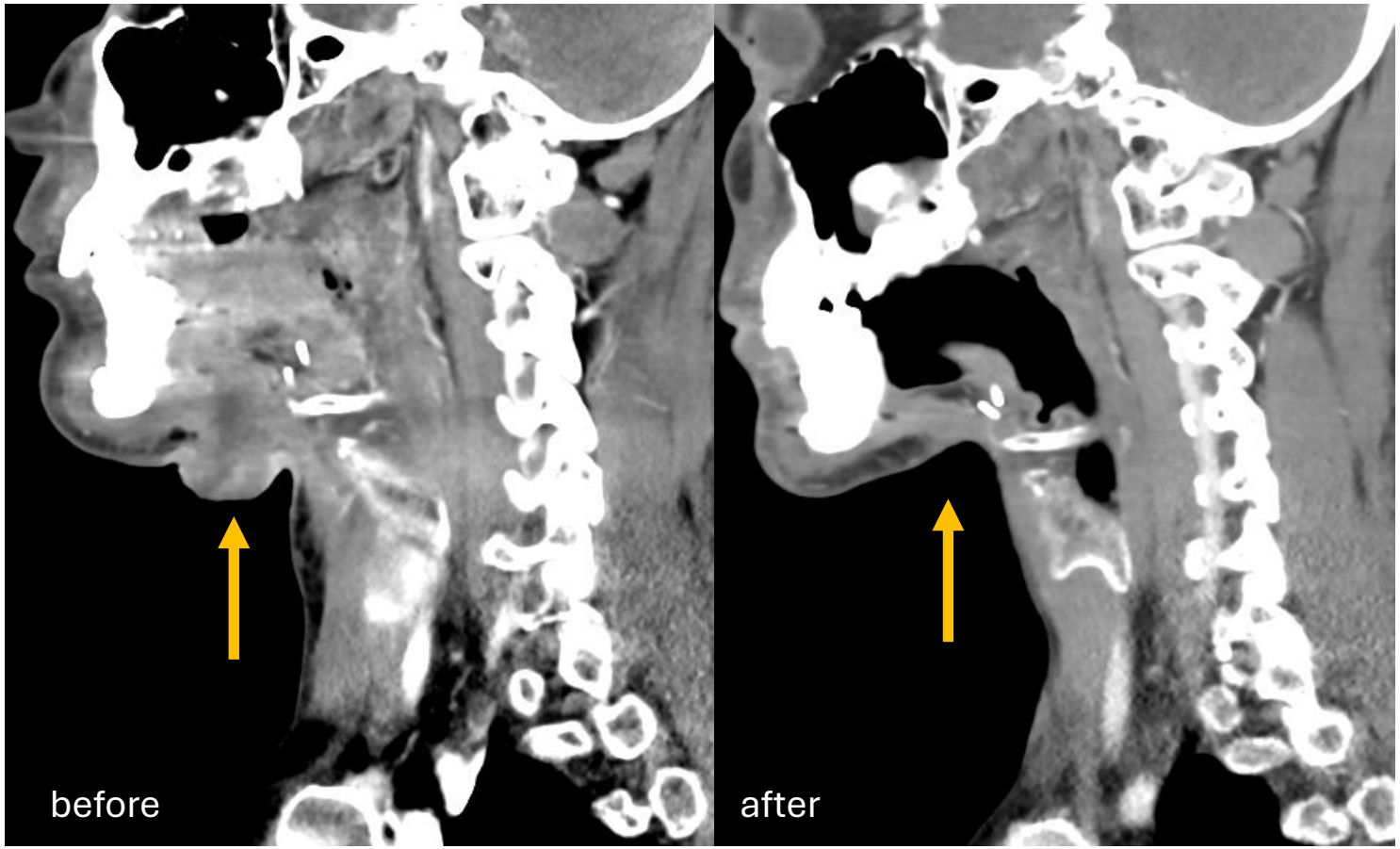
Up-Regulated in Tumor

HALLMARK PATHWAY	Gene Set (n)	NES	p.adj
INTERFERON_ALPHA_RESPONSE	90	2.42	3.07E-11
INTERFERON_GAMMA_RESPONSE	181	2.28	4.22E-12
ALLOGRAFT_REJECTION	170	2.00	2.26E-07

1. Paired biopsy spatial transcriptomics analysis conducted from n=8 paired biopsy samples amongst HPV-neg HNSCC patients in the Ph.1/1b study.
Source: O'Connell, Brenda C., et al. Cancer Research 85.8_Supplement_1 (2025): 3284-3284.
EMT = epithelial-mesenchymal transition.

FICERA Response

Deep & durable effects of FICERA + pembrolizumab observed for a patient with HPV-neg HNSCC and locoregional (LR) recurrence



- Rapid response observed for bulky tumor
- Converted from a PR to a durable CR at ~5 months
- Patient eating well and off pain medication

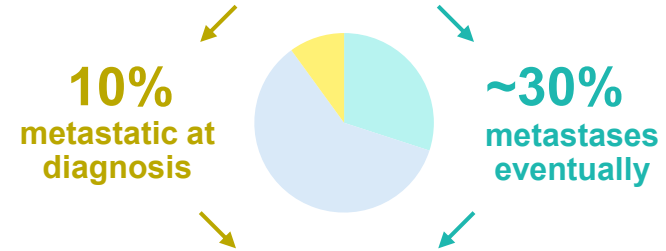
Patient treated with 2000mg Q2W ficerafusp alfa + pembrolizumab.
Source: Courtesy of Dr. Christine Chung, Moffitt Cancer Center, Tampa, FL
LR = locoregional; PR = partial response; CR = complete response

R/M HNSCC

HNSCC is a common cancer with significant unmet need for improved treatment options that extend survival

~67,000

cases of HNSCC each year in the U.S.



~23,000

cases of R/M HNSCC each year in the U.S.

~12 months	13%
median survival	5-year survival

Overview of head & neck cancers

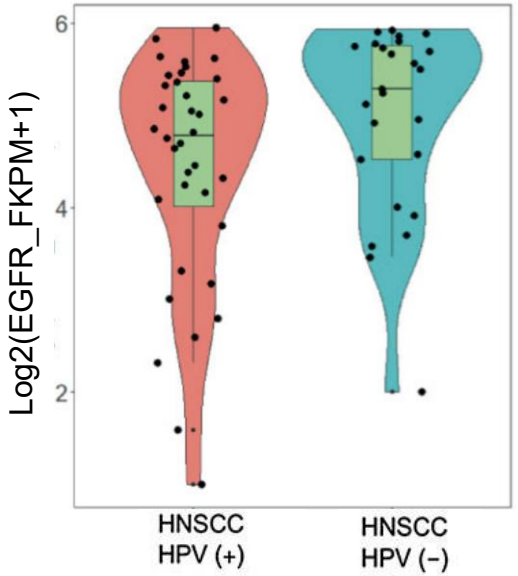
- Head and neck cancer accounts for **~4% of all cancers in the U.S.**
- **Squamous cell carcinomas represent ~90% of H&N**
- Oropharyngeal lesions are typically **tested for HPV**
  - **HPV-positive** caused by HPV infection
  - **HPV-negative** typically caused by smoking and chewing tobacco **represents 80%** of HNSCC in the R/M setting and **carries a worse prognosis** vs. HPV-positive
- **Treatment decisions are guided by CPS or PD-L1 expression** and options are limited to cetuximab, anti-PD1, chemotherapy

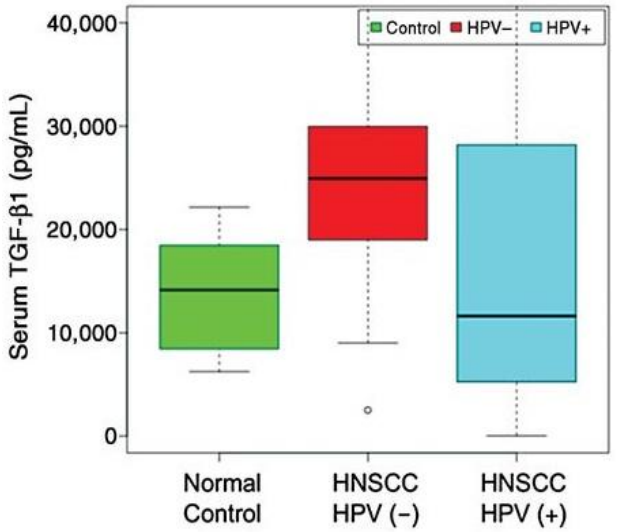
Sources: Cancer.net, Cleveland Clinic (2022); SEER 2012-2018 data; Cerner (2022); Bedi et al. Mol Cancer Ther. 2012; Acta Otorhinolaryngol Ital. 2020, KeyNote-048 ph.3 trial; ASCO (2022); DRG HNSCC (2019)
CPS = combined positive score

HPV-Neg R/M HNSCC

HPV-negative R/M HNSCC: a challenging tumor type associated with overexpression of EGFR and TGF-β

Overexpression of EGFR and TGF-β in HNSCC





HPV-negative disease demonstrates distinct biological and mutational features correlated with a poor prognosis

- **HPV-negative** disease is etiologically distinct from HPV-positive disease and associated with:
  - **Increased EGFR expression** compared to HPV-positive HNSCC patients
  - **Elevated levels of TGF-β1** in serum
  - High rate of **therapeutic resistance** (including to anti-PD-1 checkpoint inhibitors)
  - High tumor burden and **symptomatic disease**

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

HPV-Neg Survival

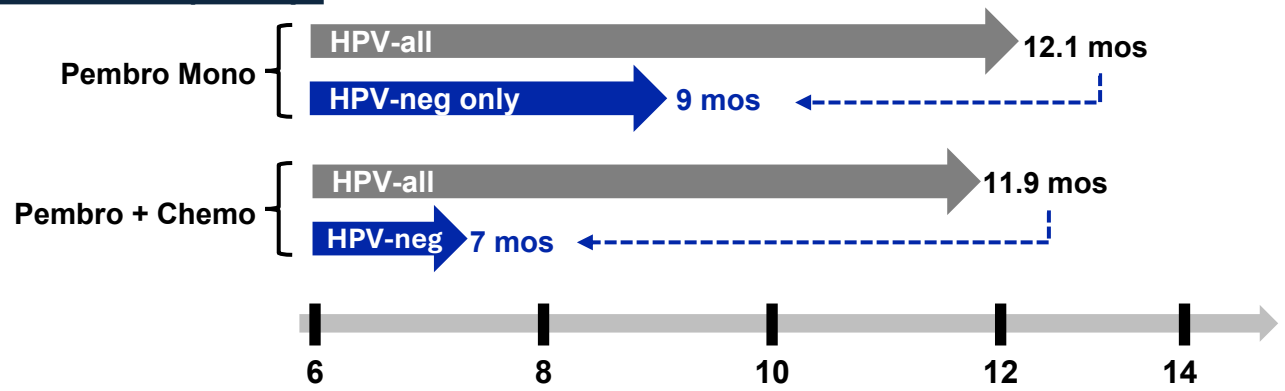
HPV-Neg patients have shown worse survival outcomes vs. HPV-pos

Historical Trial & Real-World Data

KN-048: Burtness, et al. (2019)[1]

Vasiliadou, et al. (2024)[2]

Black et al. (2023)[3]



1L HPV-negative R/M HNSCC

Median OS[2,3] = ~9 months

24-Month OS Rate[2,3] = ~20-25%

Overall survival outcomes to pembro in CPS≥1

Based on historical data. * non adjusted analysis for baseline characteristics

Sources: 1. 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.

Ph. 1b Overview

Patient Demographics and Baseline Characteristics

FICERA 1500mg IV D1, D8, D15

+

Pembrolizumab 200mg IV D1, every 21 days

Population

- 1L R/M HNSCC, **HPV-negative**
- Oral cavity, oropharynx, larynx & hypopharynx
- CPS≥1

Characteristic		Safety Set (N=30)
Age	Median (range)	63 (31-84)
Sex – n (%)	Male/Female	19/11 (63% vs. 37%)
HNSCC Primary site of disease – n (%)	Oropharynx (p16-neg)	8 (27%)
	Oral Cavity	14 (47%)
	Hypopharynx	4 (13%)
	Larynx	4 (13%)
★ **CPS – n (%)**	1-19	15 (50%)
	≥20	15 (50%)
★ **Locoregional vs. distant metastatic disease – n (%)**	LR only	9 (30%)
	LR + DM	14 (47%)
	DM only	7 (23%)
★ **Sum (mm) of Target Lesion Diameters – n (%)**	> 50	14 (47%)
	> 70	8 (27%)
ECOG Performance Status – n (%)	0 vs.1	11 vs. 19 (37% vs. 63%)

Data snapshot: March 20, 2025.
LR = locoregional; DM = distant metastases; CPS = combined positive score; ECOG, Eastern Cooperative Oncology Group; IV = intravenous.

Ph. 1b
1L HNSCC

FICERA has been generally well-tolerated with no treatment-related deaths

FICERA + pembro in 1L R/M HNSCC safety profile:

- EGFR-related AEs:
  - 76% had dermatitis acneiform, majority (27/32; 84%) are grade 1-2 in severity
- Hypothesized TGF-β-related AEs:
  - Nearly all AEs were transient Grade 1-2 local mucosal bleeds or epistaxis
- No treatment related deaths were reported

Most common (>20%) adverse events related to FICERA – summary by preferred term and maximum grade:

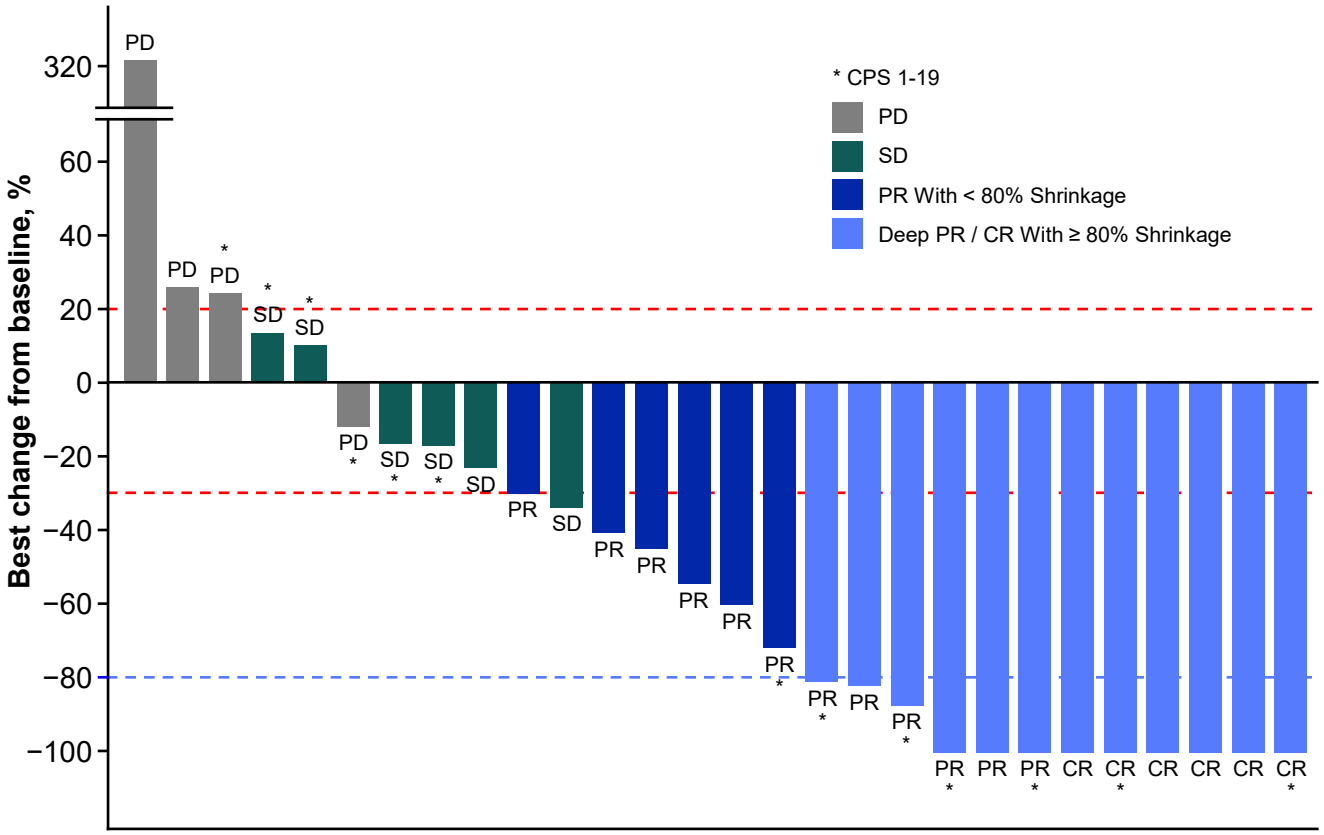
	All 1L R/M HNSCC subjects received 1500mg QW and Pembrolizumab (n=42)			
Preferred term	**All Grades**	**Grade 3**	**Grade 4**	**Grade 5**
Any Related AE	**40 (95%)**	**17 (40%)**	**1 (2%)***	**0 (0%)**
Dermatitis acneiform	32 (76%)	5 (12%)	0 (0%)	0 (0%)
Fatigue	18 (43%)	1 (2%)	0 (0%)	0 (0%)
Pruritus	18 (43%)	0 (0%)	0 (0%)	0 (0%)
Hypophosphataemia	16 (38%)	0 (0%)	0 (0%)	0 (0%)
Anaemia	15 (36%)	6 (14%)	0 (0%)	0 (0%)
Hypomagnesaemia	15 (36%)	0 (0%)	0 (0%)	0 (0%)
Dry skin	13 (31%)	0 (0%)	0 (0%)	0 (0%)
Stomatitis	10 (24%)	1 (2%)	0 (0%)	0 (0%)

*One grade 4 event of 'pericarditis' which does not appear in this table because not >20%
Data snapshot: March 20, 2025.
QW = every week.

Response Rates

FICERA drives deep responses (≥ 80% shrinkage) in HPV-neg patients

ORR with FICERA + Pembrolizumab in **HPV-neg**, CPS≥1 1L R/M HNSCC (Ph. 1b)



- **Confirmed ORR: 54% (15/28)**
  - ORR (confirmed or unconfirmed[1]): 64% (18/28)
  - Disease Control Rate: 89% (25/28)
- **Deep Responses: 80% (12/15) of responders achieved ≥ 80% tumor shrinkage**
  - CR rate: 21% (6/28)
- **Rapid Responses**
  - Median time to response: 1.4 months

Activity Across Patient Subgroups

		ORR % (N)	cORR % (N)
CPS	**CPS 1-19**	54% (7/13)	54% (7/13)
	CPS ≥ 20	73% (11/15)	53% (8/15)
Tumor Burden (SLD)	**≤ 50mm**	60% (9/15)	53% (8/15)
	> 50mm	69% (9/13)	54% (7/13)
	> 70mm	71% (5/7)	43% (3/7)

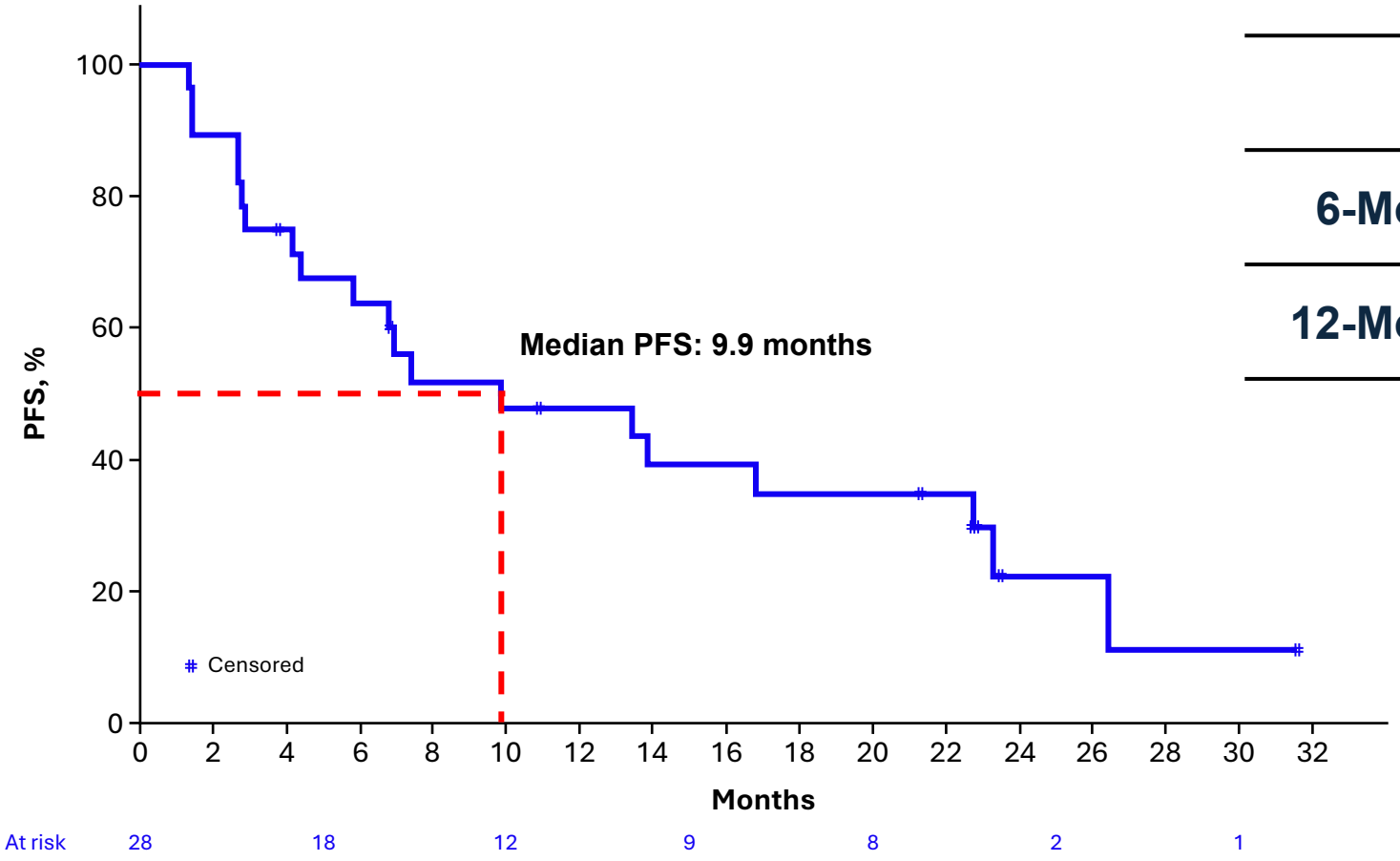
1. Three unconfirmed responses with BOR of PR with tumor shrinkage of -30%, -44%, -60%.
HPV-negative efficacy-evaluable population (n=28). Data snapshot: March 20, 2025. Investigator-assessed best overall response per RECIST 1.1.

ORR = objective response rate; cORR = confirmed objective response rate; BOR = best overall response; CR = complete response; PR = partial response; SD = stable disease; SLD = sum of target lesion diameters (mm)

mPFS

~10-month PFS with FICERA + pembrolizumab

PFS with **FICERA** + Pembrolizumab in **HPV-neg**, CPS≥1 1L R/M HNSCC (Ph. 1b)



	n=28
Median PFS	9.9 months
6-Month PFS Rate	64%
12-Month PFS Rate	48%

Historical data for pembrolizumab in HPV-all population (KEYNOTE-048):

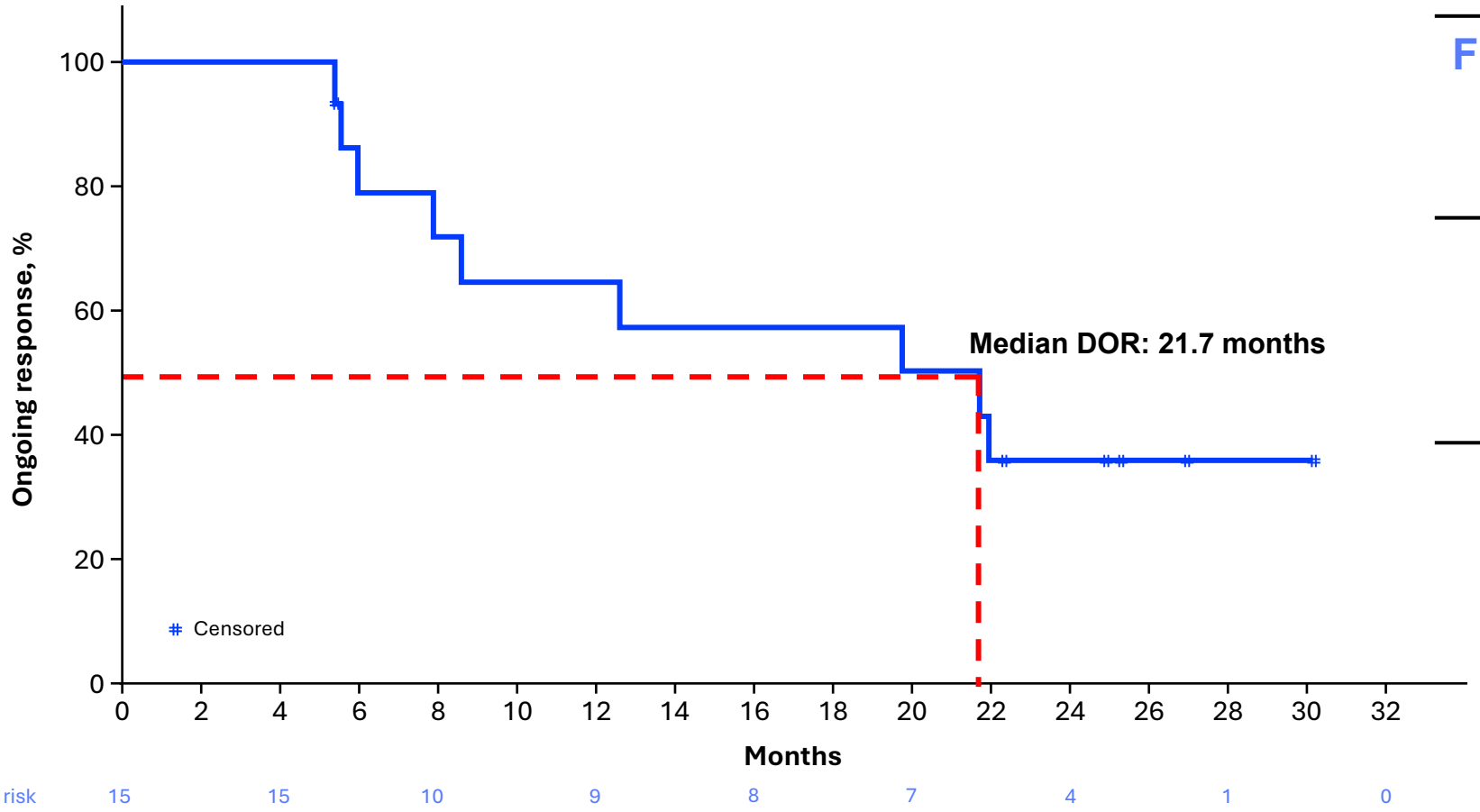
mPFS[1]: 3.2 mo (HPV-pos & HPV-neg)

HPV-negative efficacy-evaluable population (n=28). Data snapshot: March 20, 2025. Investigator-assessed best overall response per RECIST 1.1.
1. Based on historical data. No head-to-head studies have been conducted.

Durability

FICERA's tumor penetration and resistance prevention drives durable responses

Duration of Response With **FICERA** + Pembrolizumab in **HPV-neg**, CPS≥1, 1L R/M HNSCC (Ph. 1b)



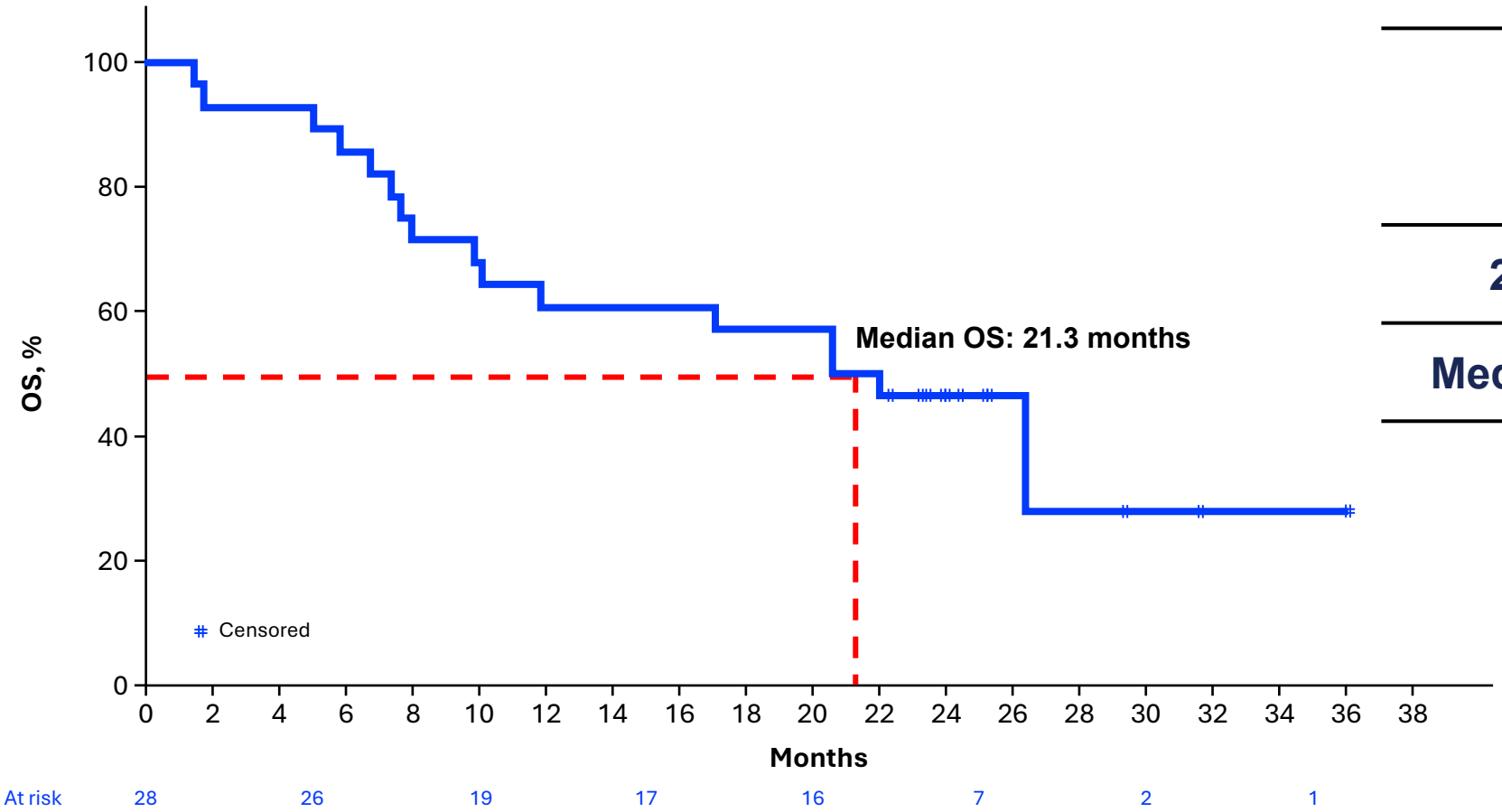
	n=15
Final Median DOR	**21.7 months***
CPS 1-19:	*17.2 months**
CPS ≥ 20:	*20.9 months**
DOR Rate:	
≥6 Months	**79%**
≥12 Months	**65%**
≥18 Months	**57%**

DOR in patients with confirmed response (n=15).
*Based on current information as of April 2025, post data snapshot. At data snapshot (March 20, 2025) final mDoR had not been reached.

Overall Survival

Prolonged Overall Survival in difficult to treat HPV-Neg patient population

OS with **FICERA** + Pembrolizumab in **HPV-neg**, CPS≥1 1L R/M HNSCC (Ph. 1b)



	n=28
Median OS	21.3 months
CPS 1-19:	*22.0 months*
CPS ≥ 20:	*20.6 months*
2-year OS Rate	46%*
Median Follow-up	25.2 months

1L HPV-negative R/M HNSCC

Median OS[2,3] = ~9 months

24-Month OS Rate[2,3] = ~20-25%

Overall survival outcomes to pembro in CPS≥1

HPV-negative efficacy-evaluable population (n=28). Data snapshot: March 20, 2025.
In the safety population (n=30), median OS was 20.6 months and the 2-year rate OS was 43%.
1. Subsequent follow-up after data snapshot in patients with ~22-23 months of follow-up confirmed that these patients remained alive at 24 months.
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.

OS = overall survival.

Ph. 1b Summary

Summary and Key Takeaways

FICERA + Pembrolizumab in **HPV-neg**, CPS≥1 1L R/M HNSCC (Ph. 1b)

FICERA + pembrolizumab is a promising 1L regimen in HPV-neg R/M HNSCC that has shown deep and durable responses

- **Manageable safety** profile
- **High ORR:** 54% ORR (n=15/28)
- **Deep responses:** 80% of responders achieved a **deep** response (≥80% tumor shrinkage)
- Median **PFS of 9.9 months**
- **Durable responses: median DOR of 21.7 months** with DOR rates of 79% at 6 months, 65% at 12 months, and 57% at 18 months
- **Prolonged overall survival:** median OS of 21.3 months, with 2-year OS rate of 46%

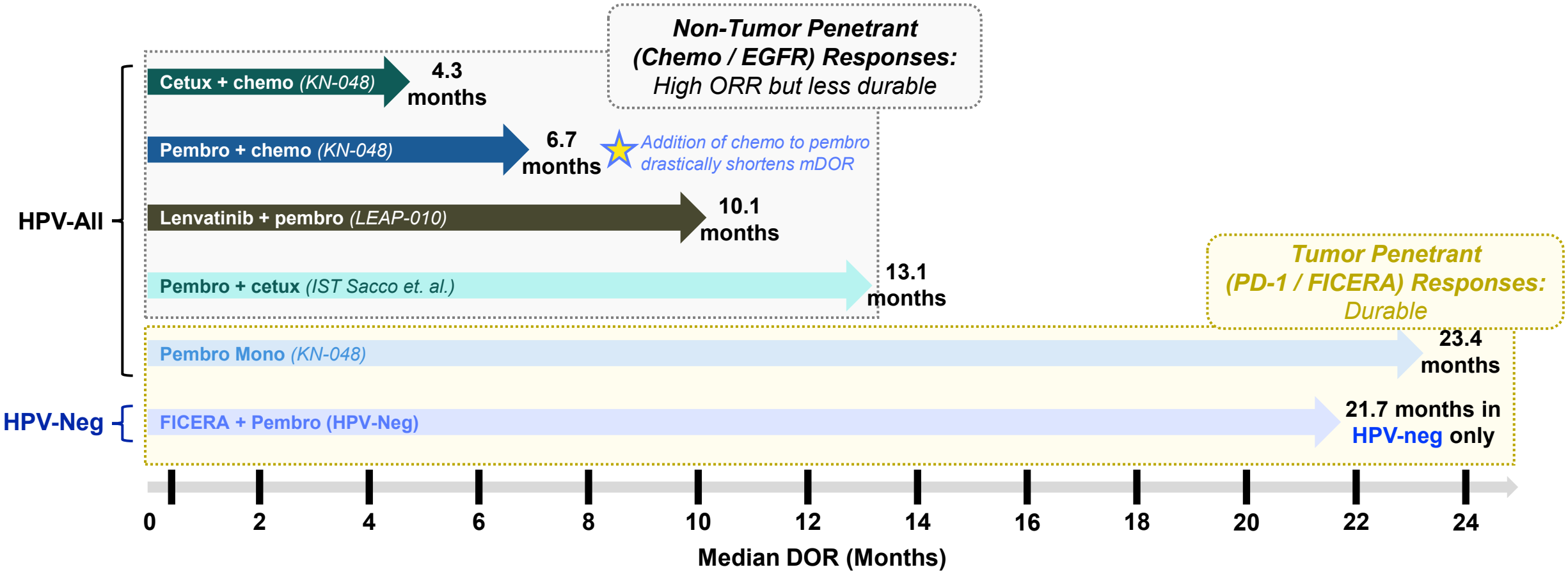
Data snapshot: March 20, 2025. Median DOR and 2-year OS rate based on current information as of April 2025, post data snapshot. At data snapshot (March 20, 2025) final mDoR had not been reached and 2-year OS rate of 46%.

Duration of Response

FICERA's tumor penetration designed to drive durability

Historical Duration of Response (DOR) Amongst Select R/M HNSCC Treatments

Median Duration of Response (DOR) in 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.

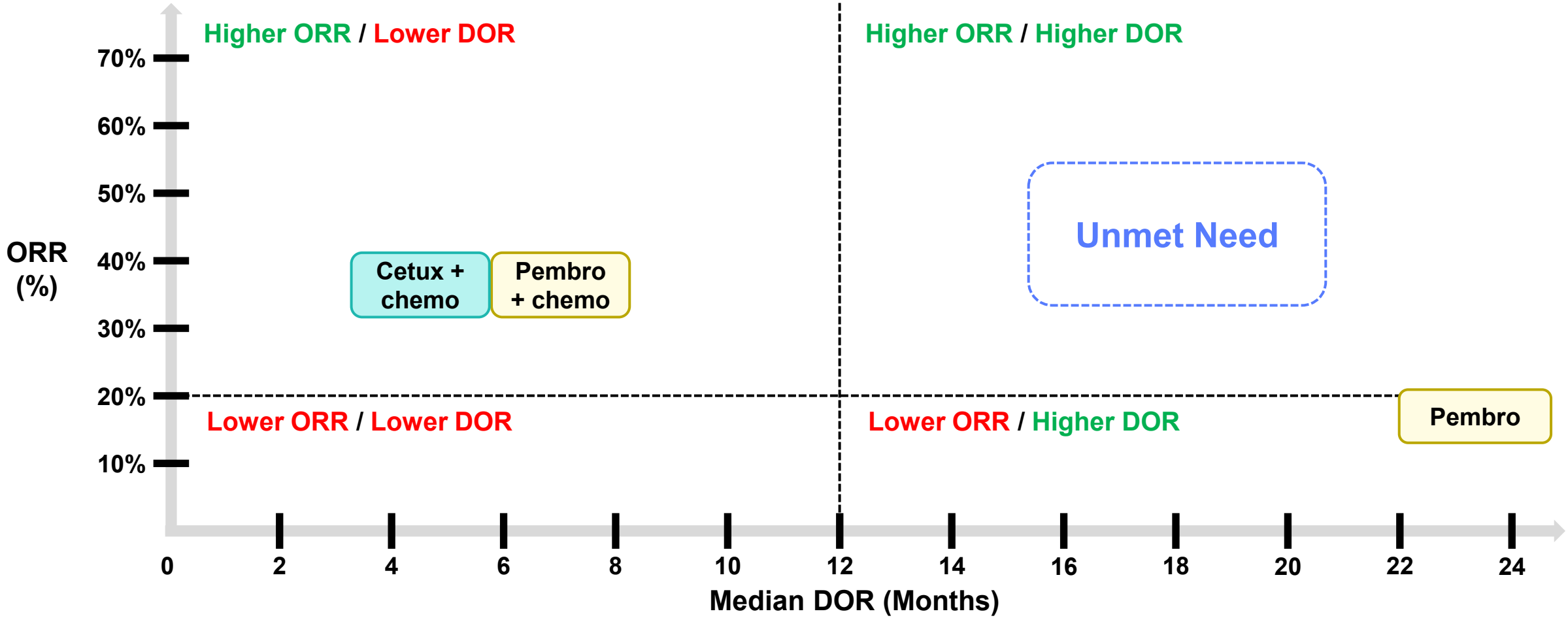
Sources: KN-048: Burtness, Barbara, et al. The Lancet 394.10212 (2019): LEAP-010: Licitra et al. MHNCS 2024, 18(5) Abs 1; Sacco, et al. The Lancet Oncology 22.6 (2021): 883-892.

FICERA Durability

FICERA's tumor penetration drives responses with depth and durability

Higher Response Rates With Durable Responses – A Void Amongst R/M HNSCC Treatment Options

Unmet need for treatments with improved ORR and durability



Based on published historical 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.

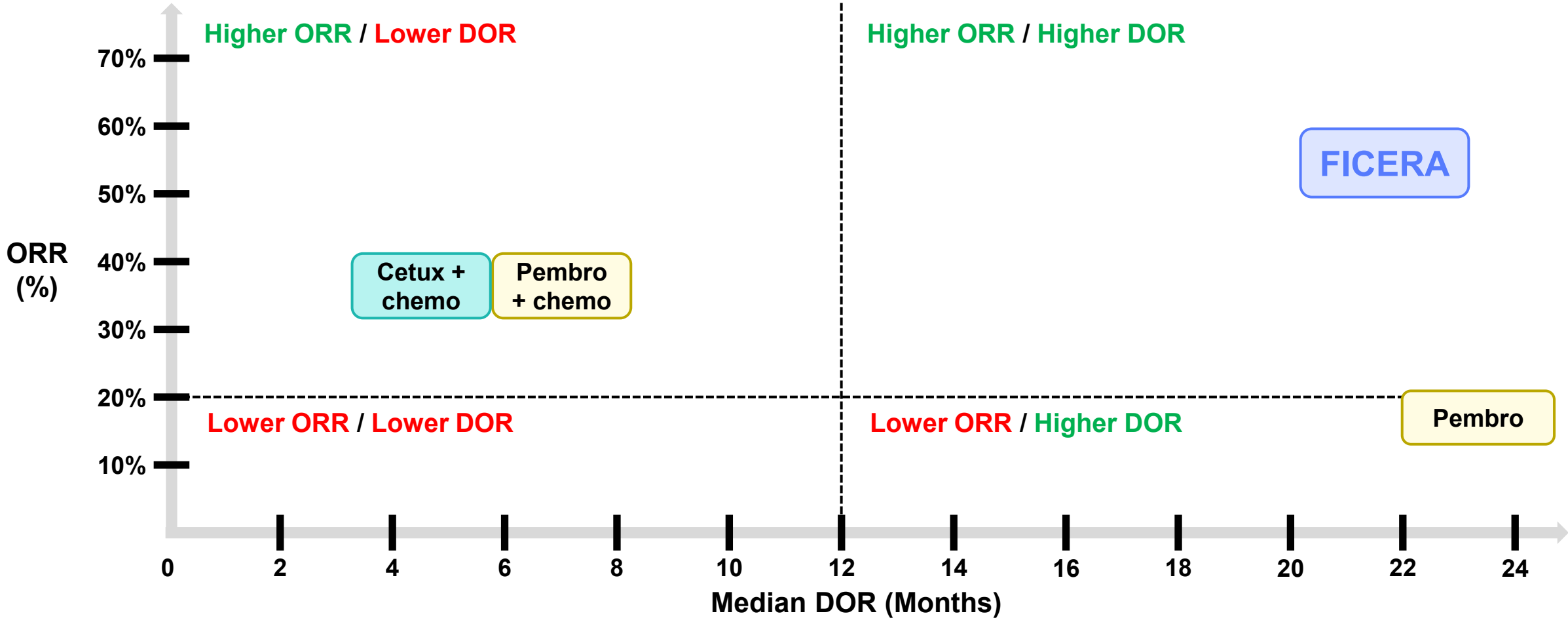
Sources: KN-048: Burtness, Barbara, et al. The Lancet 394.10212 (2019).

FICERA Durability

FICERA's tumor penetration drives responses with depth and durability

Higher Response Rates With Durable Responses – Potentially Filling A Void Amongst R/M HNSCC Treatment Options

Unmet need for treatments with improved ORR and durability



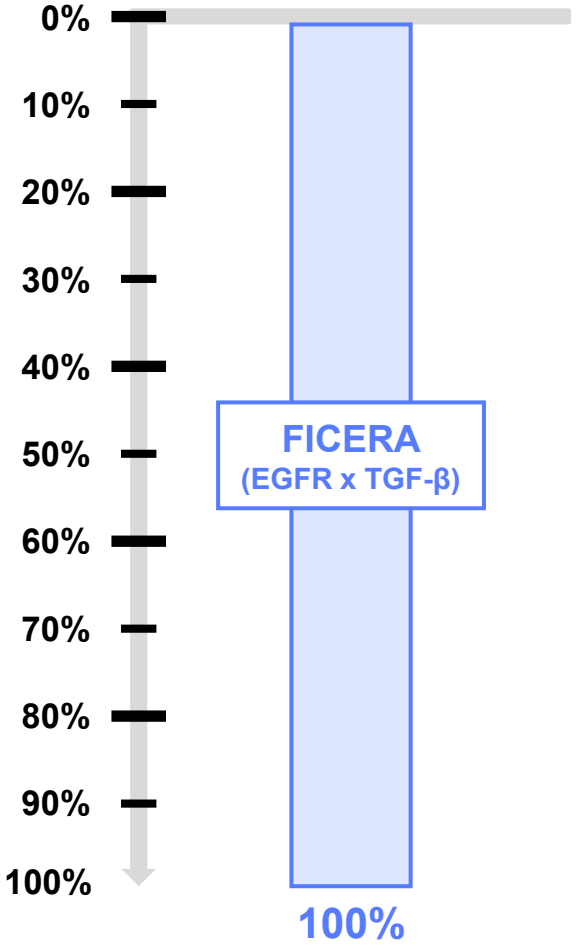
ORR and mDOR amongst HPV-neg confirmed responders (n=15/28). March 20, 2025 data snapshot. Median DOR based on current information as of April 2025, post data snapshot.
Based on published historical data. No head-to-head studies have been conducted and cross-trial comparisons may not be reliable due to differences in molecule composition, trial design, and patient population and characteristics. Sources: KN-048: Burtness, Barbara, et al. The Lancet 394.10212 (2019).

Depth Of Response

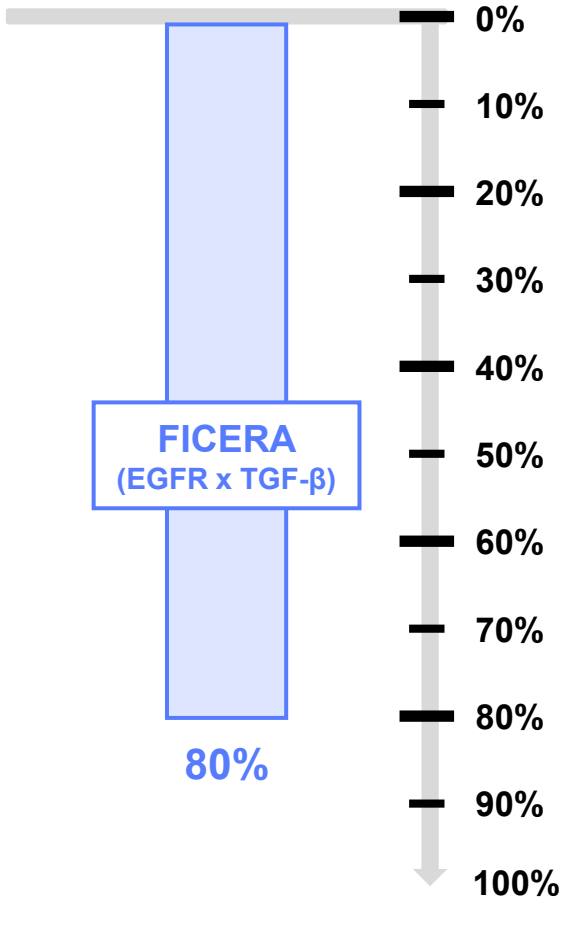
FICERA drives deep responses in HPV-Neg R/M HNSCC

Depth of response analysis: FICERA + Pembrolizumab (Ph. 1b)

Median Depth of Response



% Of Responders Achieving Deep (≥80%) Response



FICERA

*designed to drive **deep** responses*

TGF-β inhibition breaks barriers in the immune-excluded TME to enable **tumor penetration** by immune cells and drive complete tumor responses

Depth of response amongst HPV-neg confirmed responders (n=15/28).
March 20, 2025 data snapshot.

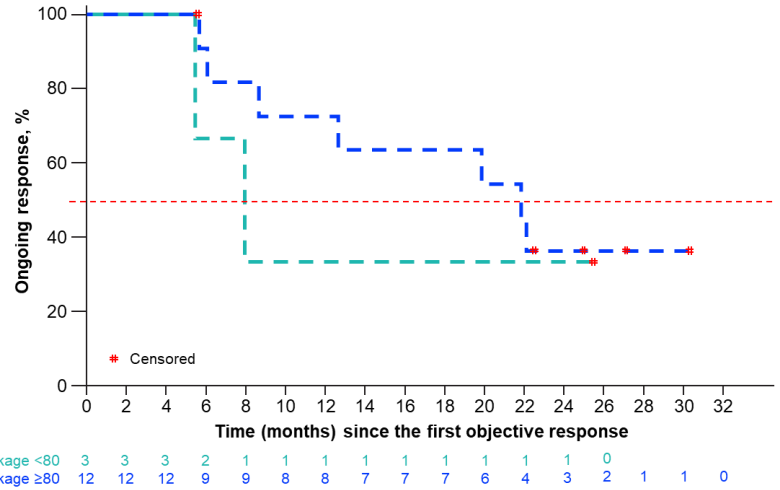
Depth → Durability

Impact of depth of response to durability and outcomes

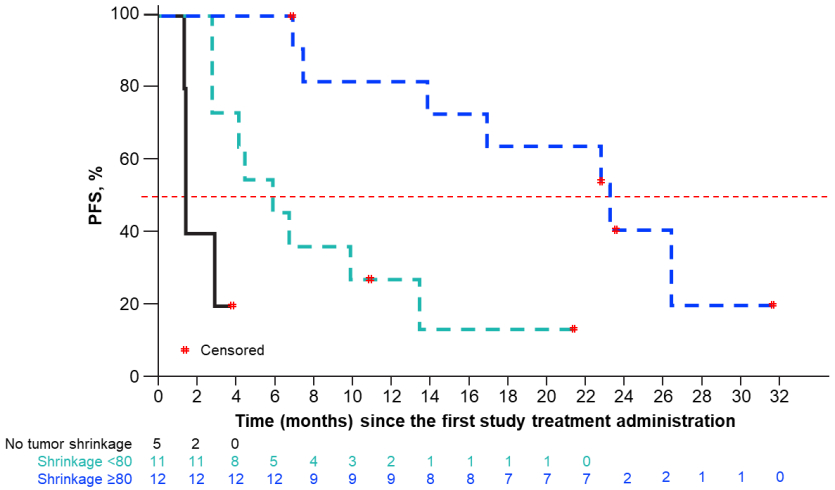
Analysis of **FICERA** + Pembrolizumab in **HPV-neg**, CPS≥1 1L R/M HNSCC (Ph. 1b)

Evaluating whether deep responses (≥80% shrinkage) impact outcomes

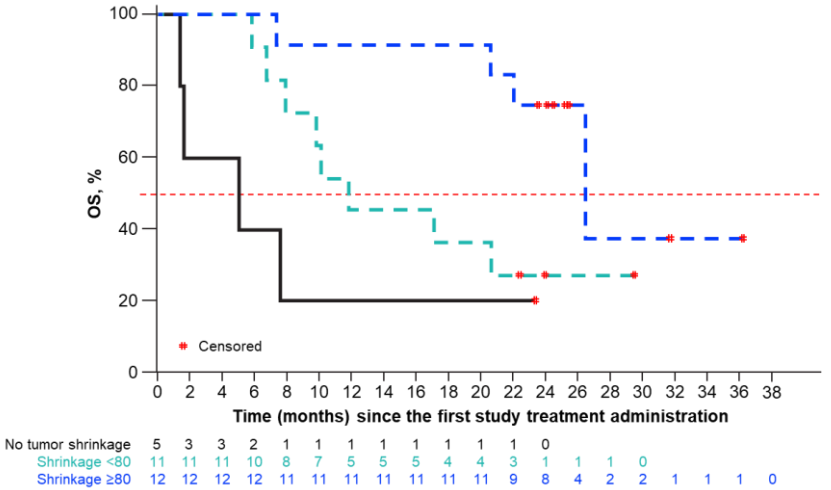
Duration of Response



Progression Free Survival



Overall Survival



- No tumor shrinkage
- Tumor shrinkage <80%
- Tumor shrinkage ≥80%

Observing deep responders (≥80% shrinkage) trend to benefits of more durable responses, longer PFS, and prolonged OS

Analysis conducted amongst HPV-neg patients (n=30).
March 20, 2025 data snapshot.

FORTIFI-HN01

FORTIFI-HN01 Phase 2/3 trial design allows for efficient path-to-market

FORTIFI

Interim Analysis: Dose Selection

Potential Accelerated Approval: Endpoint: ORR (primary)

Potential Full Approval: Endpoint: OS (primary)

R/M HNSCC
1L Setting
CPS ≥ 1
excl. HPV-positive OPSCC

R

- **FICERA** 1500mg QW + Pembro 200mg Q3W → **FICERA** optimal dose + Pembro 200mg Q3W
- **FICERA** 750mg QW + Pembro 200mg Q3W → **FICERA** optimal dose + Pembro 200mg Q3W
- Pembro 200mg Q3W

Design	Total Sample Size
Interim Analysis 1 (Dose Optimization)	n ~ 60
Interim Analysis 2 (ORR)	n ~ 415
Primary Analysis (OS)	n ~ 650

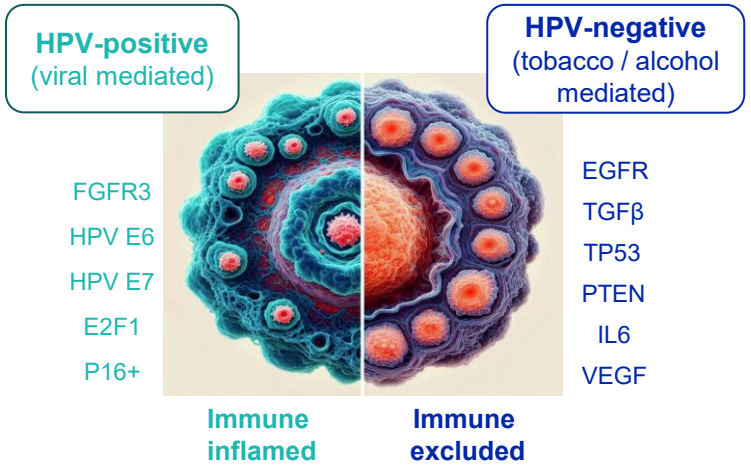
Anticipated data availability are based on current expectations and may be subject to delay.
QW = weekly; Q3W = every 3 weeks; ORR = objective response rate; OS = overall survival

FORTIFI-HN01

Deliberate focus on HPV-Neg R/M HNSCC

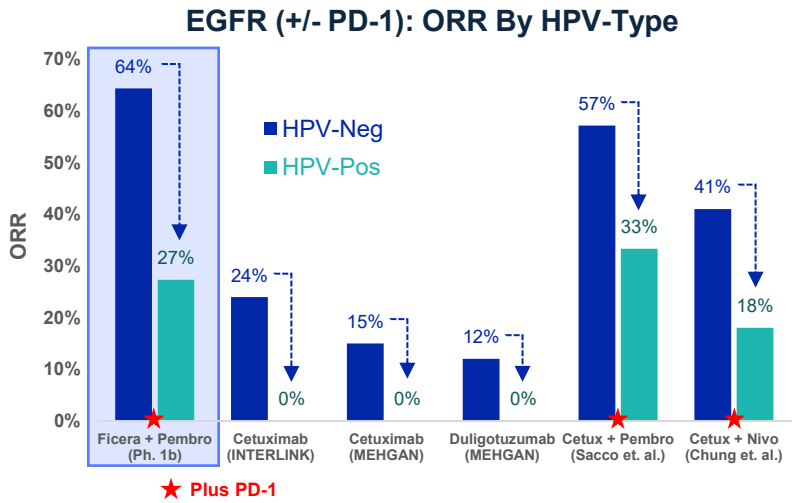
Following the science and data in R/M HNSCC

Treating HPV-Pos & HPV-Neg as two different diseases → **Understanding which patient populations benefit from FICERA** → **Precisely tailoring our approach to HPV-Neg**



"HPV-pos and HPV-neg HNSCC are two different diseases and should be viewed independently in clinical trials. Not only does disease biology differ, but also response to therapy and prognosis"

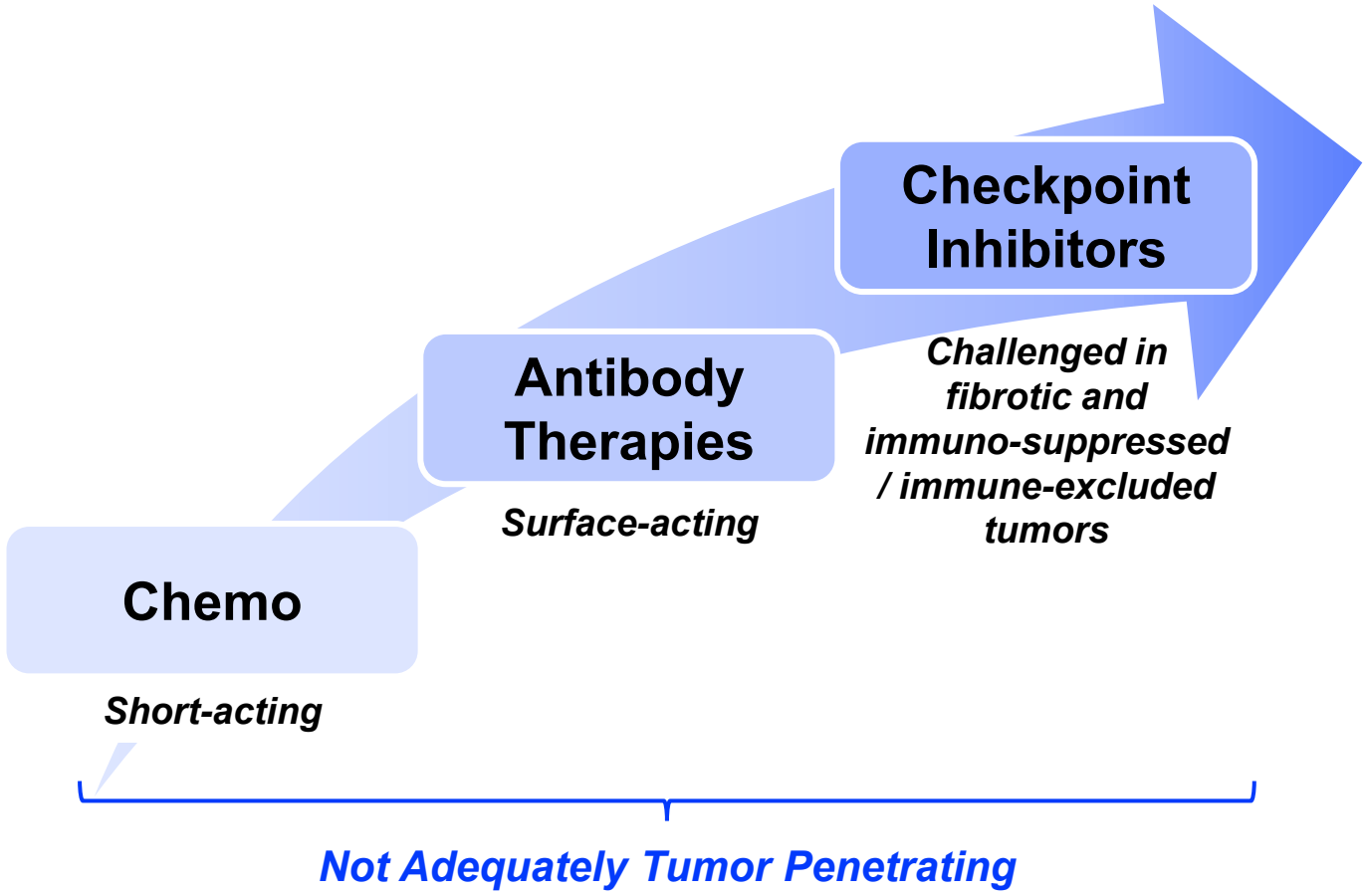
- HNSCC KOL



- ☑ Excluding HPV-Pos OPSCC[1] in FORTIFI-HN01
- ☑ Interaction with regulators to align on incorporating nucleic-acid based HPV-test
- ☑ Developing HPV companion diagnostic with a CDx partner

1. OPSCC = oropharyngeal head and neck squamous cell carcinoma (~30% of HNSCC) represents the 1 subtype of HNSCC that requires HPV testing. CDx = companion diagnostic.
Based on published historical 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: Primary market research (n=130) January 2025. INTERLINK: Fayette, J., et al. Annals of Oncology 34 (2023); MEHGAN: Fayette, Jérôme, et al. Frontiers in oncology 6 (2016); Sacco, et al. The Lancet Oncology 22.6 (2021): 883-892; Chung, Christine H., et al. Clinical Cancer Research 28.11 (2022): 2329-2338.

Tumor Penetration: A Needed Advance in Treating Solid Tumors



Next Needed Advance

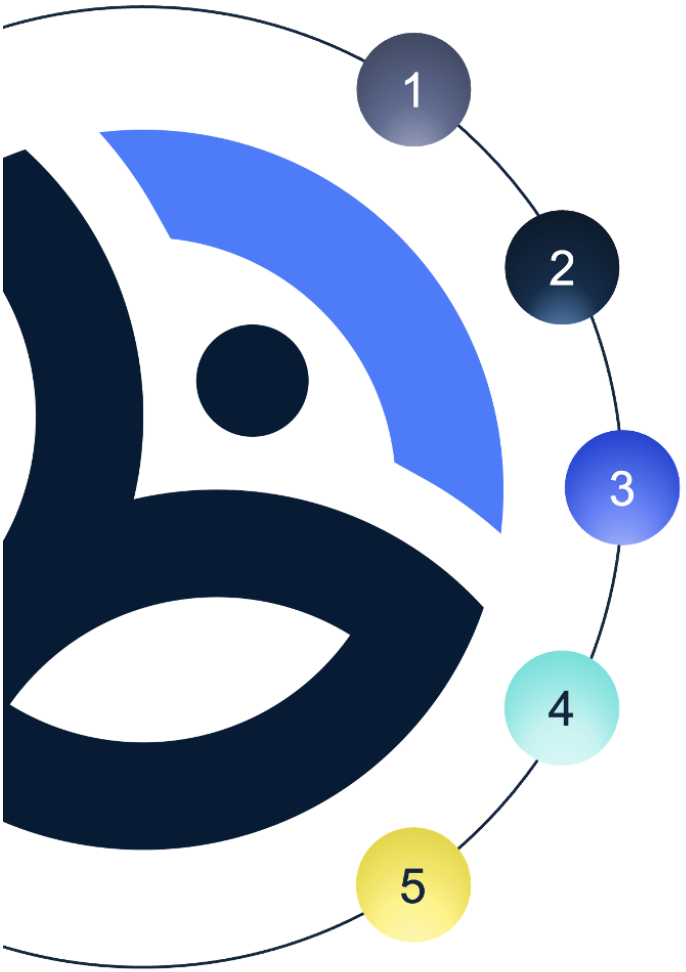
Tumor Penetrating Therapies

- **Break** down TME **barriers**
- **Reverse immune-exclusion** and **immune-suppression**
- **Change biology** of the disease
- Drive **deep and durable** responses
- **Enable** long-term **survival** benefit

Select diseases challenged by inadequate tumor penetration:
HPV-Neg HNSCC, CRC, CSCC, SCAC, PACA, GBM, Gastric, Lung, Breast, MIBC

Bicara Therapeutics Investment Highlights

*Advancing **ficerafusp alfa (FICERA)** – a bifunctional EGFR-directed antibody x TGF-β ligand trap*



FICERA designed to enable tumor penetration by breaking barriers in the tumor microenvironment to drive deep and durable responses

FICERA + pembro offers a potential new 1L therapy for HPV-negative R/M HNSCC; FORTIFI-HN01 Ph. 2/3 trial ongoing and enrolling

Significant market opportunity with ~23,000 cases of R/M HNSCC annually in the U.S. and a significant unmet need for better treatment options (13% 5yr survival)

Expansion into other squamous cell carcinomas and solid tumors, with encouraging clinical activity observed in Ph. 1b expansion cohorts to date

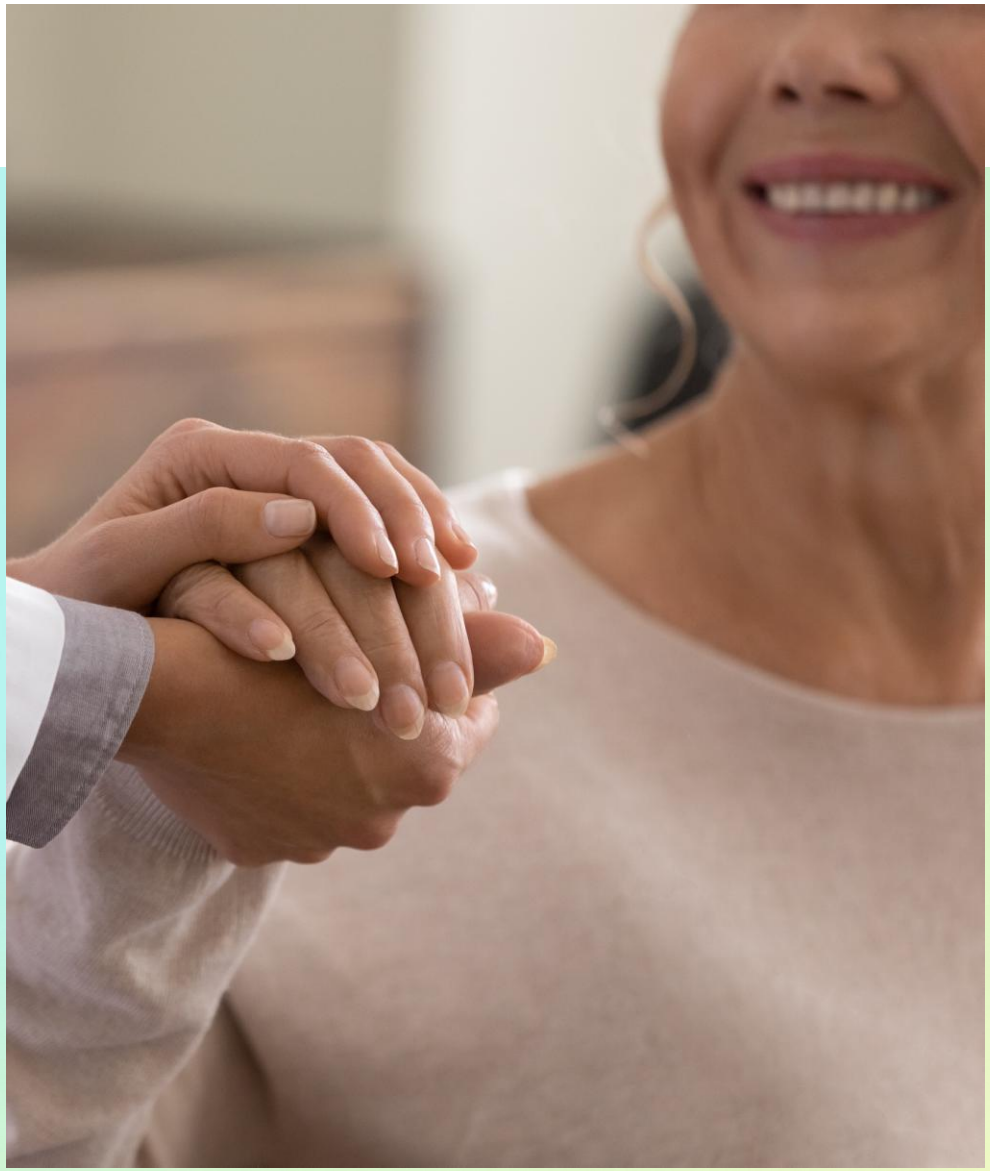
Seasoned management team with a strong track record of execution; robust financial position with ~$462M in cash and equivalents[1]

1. Cash and cash equivalents as of 3/31/25.

BICARA THERAPEUTICS™

ASCO 2025 Clinical Update

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



June 2025