UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): January 13, 2025

Bicara Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-42271	85-2903745
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

116 Huntington Avenue,
Suite 703 Boston, MA 02116
(Address of principal executive offices and zip code)

(617) 468-4219
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value	BCAX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act.

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 - Regulation FD Disclosure.

Bicara Therapeutics Inc. (the "Company") is furnishing a corporate presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company intends to use from time to time in meetings with investors and others beginning on January 13, 2025. The corporate presentation will also be available in the investor relations section of the Company's website at https://ir.bicara.com/.

The information set forth under Item 7.01 and in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 - Financial Statements and Exhibits

(d) The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Corporate presentation of Bicara Therapeutics Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized on this 13th day of January, 2025.

Bicara Therapeutics Inc.

By: /s/ Claire Mazumdar
Name: Claire Mazumdar
Title: Chief Executive Officer

BICARA THERAPEUTICS™

Fighting cancer with precision and power.

Corporate Presentation | January 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 product development activities for ficerafusp alfa and ongoing clinical trials; the ability of clinical trials to demonstrate safety and efficacy of ficerafusp alfa; the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of ficerafusp alfa; our ability to develop and advance our potential future product candidates and programs; our ability to pursue and execute our strategy for our indications, business, programs and technology; our ability to leverage existing programs and to progress additional programs, the timing of investigational new drug application submissions, our and our collaborators' ability to protect our intellectual property for our products; our ability to enter into future license agreements and collaborations; regulatory developments; and our ability to attract and retains key scientific and management personnel. 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.

Bicara Therapeutics Investment Highlights

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

1. **FICERA + pembro offers a potential new chemo-free 1L therapy for HPV-negative R/M HNSCC that may meaningfully improve upon current standard of care**
2. **FORTIFI-HN01 Ph. 2/3 trial initiated December 2024; potential accelerated approval pathway based on an interim ORR analysis**
3. **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)**
4. **Expansion into other squamous cell carcinomas and solid tumors, with encouraging clinical activity observed in Ph. 1b expansion cohorts to date**
5. **Seasoned management team with a strong track record of execution; robust financial position with ~$521M in cash and equivalents[1]**

1. Cash and cash equivalents as of 9/30/24.

R/M HNSCC = recurrent / metastatic head and neck squamous cell carcinoma; ORR = overall response rate.

Bicara Therapeutics is led by a seasoned and driven management team

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

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

Ivan Hyep, MBA
Chief Financial Officer

Lara Meisner, J.D.
Chief Legal Officer

David Raben, M.D.
Chief Medical Officer

Rachel Salazar, D.H.Sc.
SVP, R&D Strategy & Operations

Jeltje Schulten, M.D., MBA
SVP, Clin. & Med. Affairs

Sathish Hasige, Ph.D.
SVP, Technical Ops & Supply Chain

Jean-Paul Rodrique
SVP, Quality

Maximizing the value of FICERA across HNSCC & other solid tumors

Indication	Phase 1/1b	Phase 2/3	Status
1L R/M Head and Neck Squamous Cell Carcinoma			
HPV-neg: Pivotal Ph. 2/3: FORTIFI-HN01 – 1500mg QW (+ pembro)			Trial initiated December 2024
HPV-neg: Ph. 1b Expansion Cohort – 1500mg QW (+ pembro)			**Updated data expected in 1H 2025**
HPV-neg: Ph. 1b Expansion Cohort – 750mg QW (+ pembro)			Trial ongoing
HPV-neg: Ph. 1b Expansion Cohort – CPS=0 (+ pembro)			Trial ongoing
HPV-pos: HPV-Positive Smokers Ph. 1b Expansion Cohort (+ pembro)			Expect to initiate trial in 1H 2025
Earlier-Line Head and Neck Squamous Cell Carcinoma			
Neoadjuvant / Locally Advanced HNSCC (combo with RT and/or anti-PD-1)			Expect to initiate trial in 2025
Other EGFR+ Solid Tumors			
Ph. 1b Expansion: 2L+ Squamous Cancer of the Anal Canal (+ pembro)			**Data to be presented in Q1 2025**
Ph. 1b Expansion: 2L+ Cutaneous Squamous Cell Carcinoma (monotherapy)			**Updated data expected in 1H 2025**
Ph. 1b Expansion: 3L+ Colorectal Cancer (RAS / BRAF wild type)			Expect to initiate trial in 2025

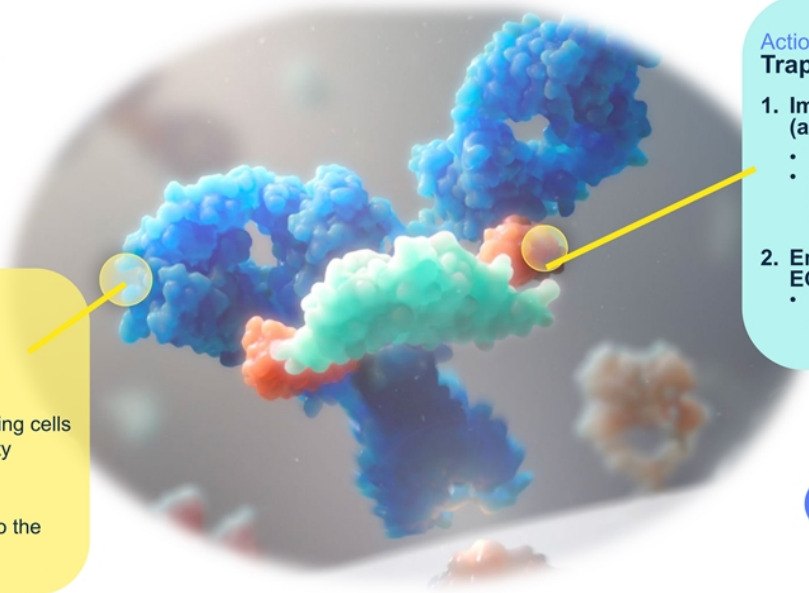
HNSCC = head and neck squamous cell carcinoma, QW = once weekly, CPS = combined positive score, RT = radiation therapy.

MOA

FICERA's bifunctional design targets EGFR and TGF-β directly in the TME to drive a differentiated clinical profile

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. **Improves immune response (anti-PD-1 Synergies)**
   - Relieves immune suppression
   - Blocks cancer associated fibroblasts, reducing fibrosis and T-cell exclusion
2. **Enhances EGFR inhibition (anti-EGFR Synergies)**
   - Prevents known EGFR resistance mechanism (via EMT)

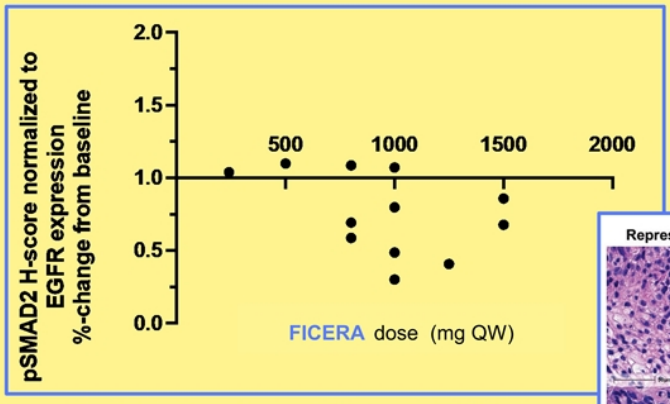
Increase depth and duration of response

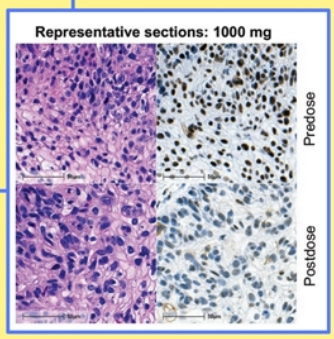
EGFR = epidermal growth factor receptor, ADCC = antibody dependent cell-mediated cytotoxicity, TME = tumor microenvironment, EMT = epithelial-mesenchymal transition

MOA

FICERA clinical biomarkers demonstrated tumor target engagement in Ph. 1/1b and predicted MOA

Statistically significant inhibition of tumor TGF-β observed at FICERA doses >750mg via pSMAD2 levels





First definitive demonstration of pSMAD2 knockdown in patient tumors by a TGF-β inhibitor

Dose Expansion

FICERA dose expansion strategy driven by strong biologic rationale for the dual inhibition of both EGFR and TGF-β

Based on preliminary efficacy and safety & tolerability data, **1500mg QW FICERA** was chosen as recommended dose to take into dose expansion cohorts

MTD was not reached

Dose Expansion

FICERA monotherapy

2L+ CSCC
*n = 12 + 25**
FICERA – 1500mg QW

FICERA + PEMBRO

☑ R/M 1L HNSCC
*n = 13+ 26**

☑ 2L+ SCAC

FICERA – 1500mg QW

**Simon 2-stage design*

☑ *Enrollment complete*

MTD = Maximum Tolerated Dose

Market Opportunity

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)

Market Opportunity

The patient journey in HNSCC

1 Symptoms

Patient presents to primary care/ENT with symptoms:
Pain, swallowing difficulty, mucosal bleeding, asthenia, weight loss

2 Testing and Staging

Work-up may include:
Laryngoscopy, biopsy, imaging (CT scan, MRI)
HPV/p16 testing in Oropharynx

Diagnosis of cancer

3 MDT & Treatment

Multi-disciplinary (med-onc, rad-onc, surgeon) decision:
Locally Advanced HNSCC: Curative-intent surgery and/or chemo-radiation
M1 disease: palliative treatment & Molecular testing: PD-L1 CPS

LA HNSCC

50% Relapse within 2 years after treatment for LA HNSCC[1]

4 Relapse

Metastatic at diagnosis

1L R/M HNSCC

CPS = 0

Platinum-based + cetuximab

Study

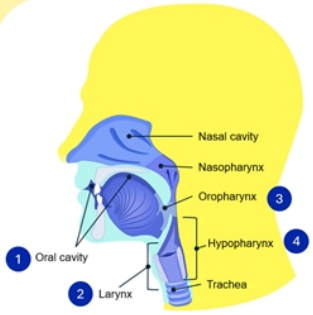
CPS≥1

Pembrolizumab mono

Platinum + 5FU + Pembro[2]

Study

Initial focus



1. HNSCC population who relapse <6 months after CRT receive nivolumab as 1L treatment
2. Choice of pembro + chemo (platinum + 5FU) is at the physician's discretion and is typically more common in the CPS<20 group and/or rapidly progressing disease.

Market Opportunity

HNSCC patients suffer significant symptomology and represent a major unmet need

Patients experience acute and chronic toxicities after surgery and/or chemo-radiation

Acute side effects

- **Painful sores** in the mouth or throat (oral mucositis) and dermatitis
- **Difficulty swallowing** (dysphagia) from surgery or chemo-RT
- **Feeding tube** may be required for nutritional support during Chemo-RT for many patients
- **Dry mouth** (xerostomia)
- **Speech/voice difficulties** and managing the stoma after laryngectomy

Chronic side effects

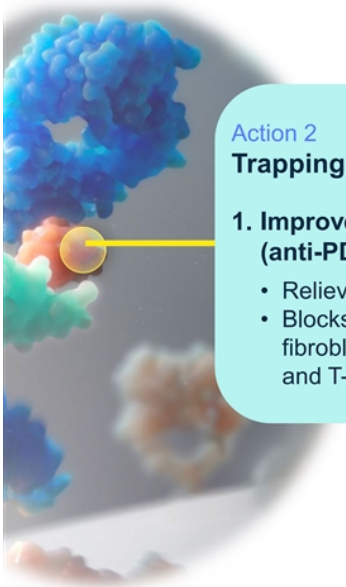
- Trismus – **difficulty opening the jaw** / nerve damage to jaw
- **Osteoradionecrosis** – breakdown of the mandible
- Radiation based **fibrosis causing tissue damage**
- **Neuropathies** from surgery/chemotherapy and radiation
- **Lymphedema** (tissue swelling)
- Nutritional deficits

Source: Head and Neck Cancer Alliance.

Chemo-RT = chemoradiotherapy

1L HNSCC

FICERA + pembro R/M HNSCC expansion cohort based on mechanistic synergies with anti-PD-1 and IST precedent



Action 2

Trapping TGF-β

1. Improves immune response (anti-PD-1 Synergies)

- Relieves immune suppression
- Blocks cancer associated fibroblasts, reducing fibrosis and T-cell exclusion

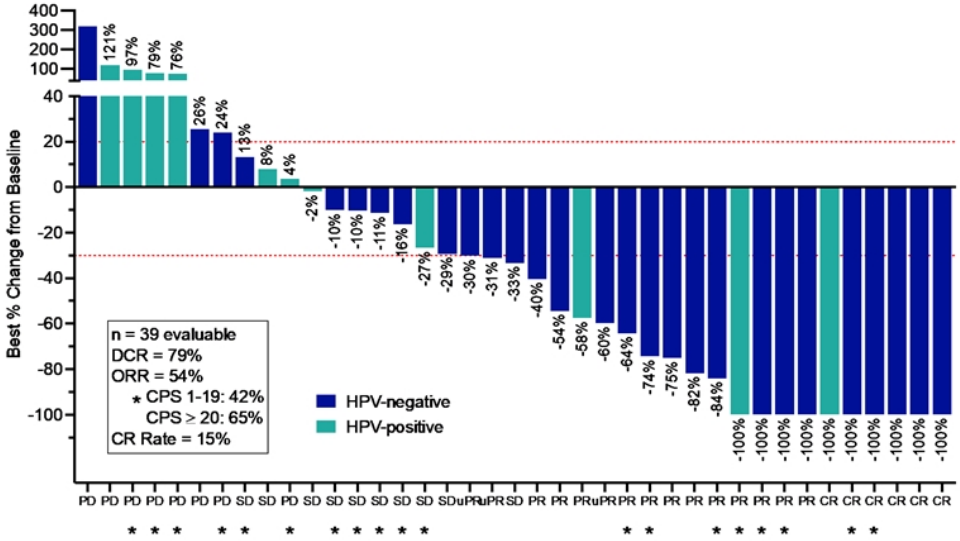
Two ISTs exploring anti-PD-1 + cetuximab help inform FICERA registration path

Study	KEYNOTE-048[1]	*Sacco, et al 2021*	*Chung, et al 2022*
Published	THE LANCET	THE LANCET Oncology	CLINICAL CANCER RESEARCH
Drug(s)	Pembro	Cetux + pembro	Cetux + nivo
Phase	Phase 3	Phase 2	Phase 1/2
Size	N=257	N=33	N=43
Design	Randomized, open-label, three-arm study	Open-label, single-arm	Open-label, single-arm
Efficacy Metrics			
ORR	19%	48%	37%
CRR	5%	3%	2%
mPFS	3.2 months	6.5 months	6.2 months
mOS	12.3 months	18.4 months	20.2 months

1. Data shown only for patients with CPS ≥ 1 treated with pembrolizumab monotherapy.

1L HNSCC

FICERA + pembro demonstrates compelling activity and depth of response in 1L R/M HNSCC regardless of HPV status



FICERA + pembro expansion in R/M HNSCC

- **Population**
  - 1L R/M HNSCC
  - Oral cavity, oropharynx, hypopharynx & larynx
  - HPV testing required for oropharyngeal cancer
  - CPS≥1
- **54% (21/39) ORR in CPS≥1 patients**
  - Historical[1] pembro mono ~19% ORR
- **15% (6/39) CR Rate in CPS≥1 patients**
  - 4 additional patients with -100% PRs**

Note: Out of 42 patients, 3 patients were non-efficacy evaluable. Best overall response (investigator-assessed according to RECIST (Response Evaluation Criteria in Solid Tumors) version 1.1). CPS=combined positive score, CR=complete response, DCR=Disease Control Rate, HPV=human papilloma virus, ORR=Overall response rate, PR=partial response, uPR=unconfirmed partial response, SD=stable disease

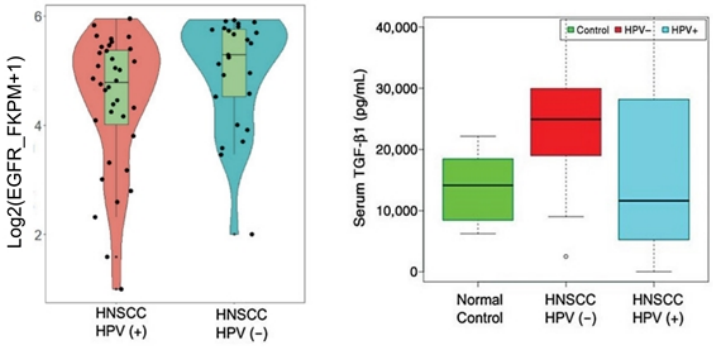
1. Based on historical data. No head-to-head studies have been conducted.

** May still have nodal disease

Market Opportunity

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



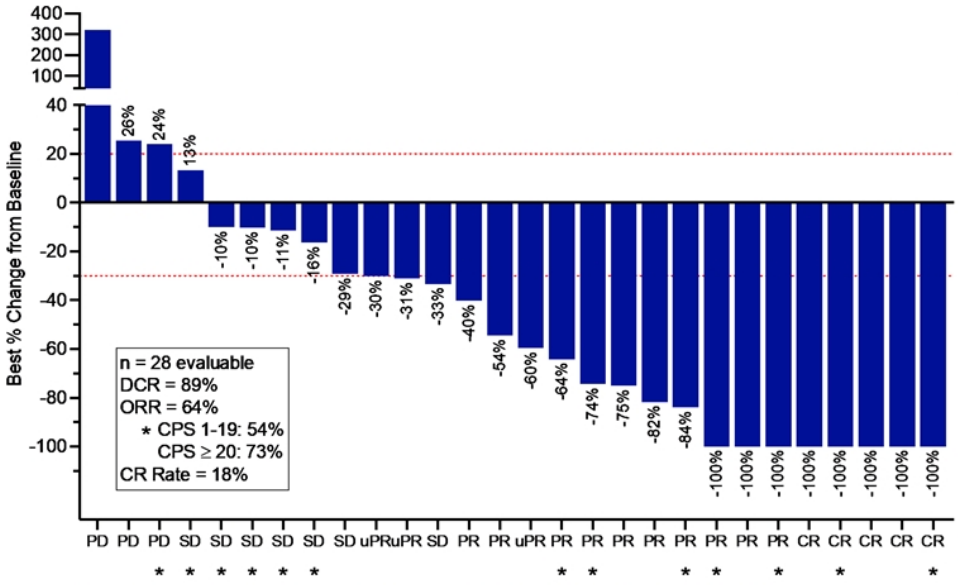
HPV-negative disease demonstrates distinct biological and mutational features correlated with a poor prognosis

- **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).

1L HNSCC

FICERA + pembro demonstrates significantly improved activity and depth of response in HPV-negative CPS≥1 1L R/M HNSCC



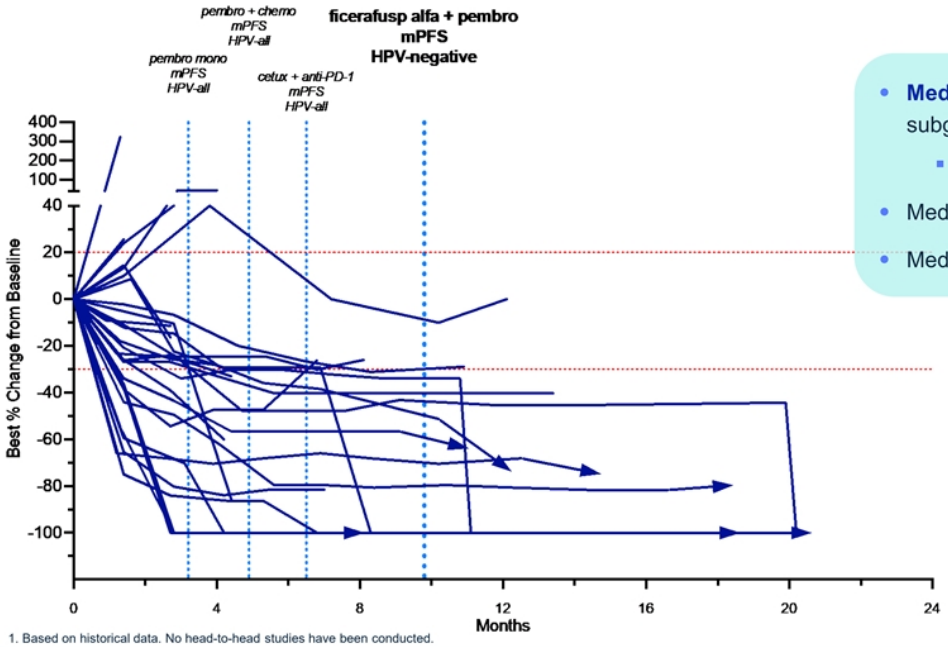
In HPV-negative patients:

- **64% (18/28) ORR observed, CPS≥1 patients**
  - Historical[1] pembro mono expected to be ~19% ORR
  - 15/18 confirmed responses
- **High response rates in subgroups that are typically refractory to checkpoint therapy:**
  - 70% (14/20) ORR in patients with locoregional disease involvement
  - 54% (7/13) ORR in CPS low (1-19)
- **18% (5/28) Complete Response (CR) rate**
  - Pembro and pembro + cetux have historically[1] achieved a ~3-5% CR rate

Note: Best overall response (investigator-assessed according to RECIST (Response Evaluation Criteria in Solid Tumors) version 1.1).
CPS=combined positive score, CR=complete response, DCR=Disease Control Rate, HPV=human papilloma virus, ORR=Overall response rate, PR=partial response, uPR=unconfirmed partial response, SD=stable disease
1. Based on historical data. No head-to-head studies have been conducted.

1L HNSCC

HPV-negative 1L HNSCC suggests improved median PFS over pembro monotherapy supportive of TGF-β hypothesis



- **Median PFS of 9.8 months** in **HPV-negative** subgroup
  - 57% (16/28) of pts with PFS>6 months
- Median duration of response (DOR) not yet reached
- Median overall survival (OS) not yet reached

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

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

1. Based on historical data. No head-to-head studies have been conducted.

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 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 (>10%) related adverse events – 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 3-4	Grade 5
Any Related AE	**40 (95%)**	**17 (40%)**	**0 (0%)**
Dermatitis acneiform	32 (76%)	5 (12%)	0 (0%)
Fatigue	18 (43%)	2 (5%)	0 (0%)
Pruritus	17 (40%)	0 (0%)	0 (0%)
Anaemia	15 (36%)	6 (14%)	0 (0%)
Hypophosphataemia	16 (38%)	0 (0%)	0 (0%)
Hypomagnesaemia	15 (36%)	0 (0%)	0 (0%)
Dry skin	13 (31%)	0 (0%)	0 (0%)
Stomatitis	10 (24%)	1 (2%)	0 (0%)
Infusion related reaction	8 (19%)	1 (2%)	0 (0%)
Hypokalaemia	8 (19%)	0 (0%)	0 (0%)
Nausea	7 (17%)	0 (0%)	0 (0%)
Proteinuria	7 (17%)	0 (0%)	0 (0%)
Epistaxis	6 (14%)	0 (0%)	0 (0%)
Lipase increased	6 (14%)	0 (0%)	0 (0%)
Skin fissures	6 (14%)	0 (0%)	0 (0%)
Decreased appetite	6 (14%)	1 (2%)	0 (0%)
Headache	5 (12%)	1 (2%)	0 (0%)
Rash maculo-papular	5 (12%)	1 (2%)	0 (0%)
Diarrhoea	5 (12%)	0 (0%)	0 (0%)
Aspartate aminotransferase increased	5 (12%)	0 (0%)	0 (0%)
Gingival bleeding	5 (12%)	0 (0%)	0 (0%)

1L HNSCC

FICERA 1L HNSCC Ph.1b expansion supports a pivotal trial with path to accelerated approval

FICERA has demonstrated a strong clinical profile

- **64% ORR in HPV-negative**, CPS≥1 R/M HNSCC in combination with pembro vs. ~19% historical[1] pembro monotherapy
- **18% complete response rate** vs. ~3-5% with available therapies (pembro and pembro + cetux)
- **mPFS of 9.8 months** (vs. 3.2 months for pembro monotherapy in HPV+/-)
- **Generally well tolerated safety profile**

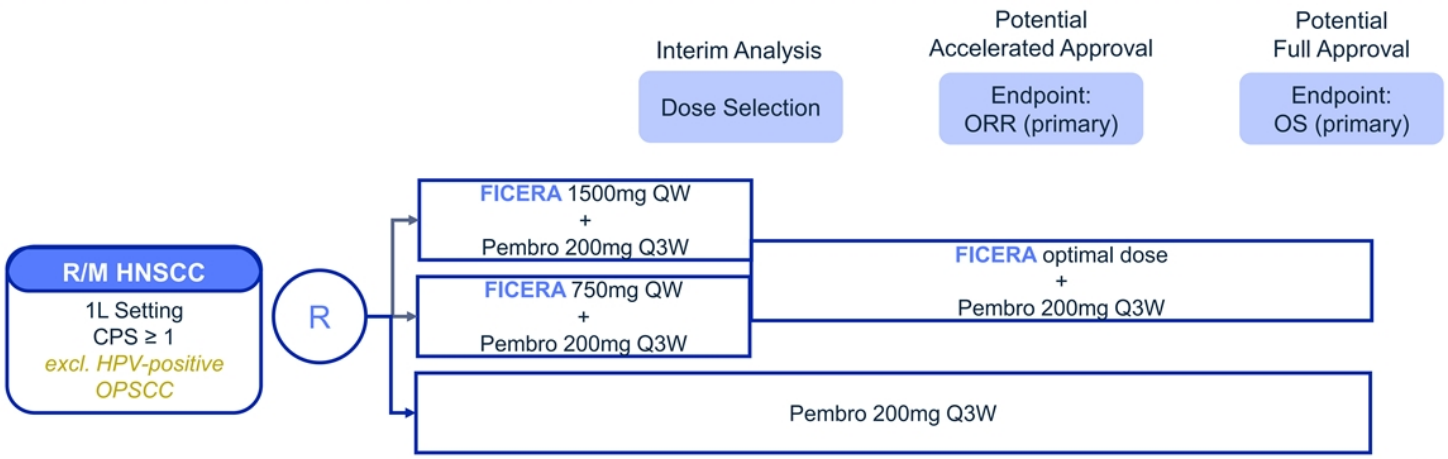
FORTIFI-HN01 Ph. 2/3 trial initiated December 2024

FDA feedback supports potential accelerated approval pathway

1. Based on historical data. No head-to-head studies have been conducted.

FORTIFI-HN01

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



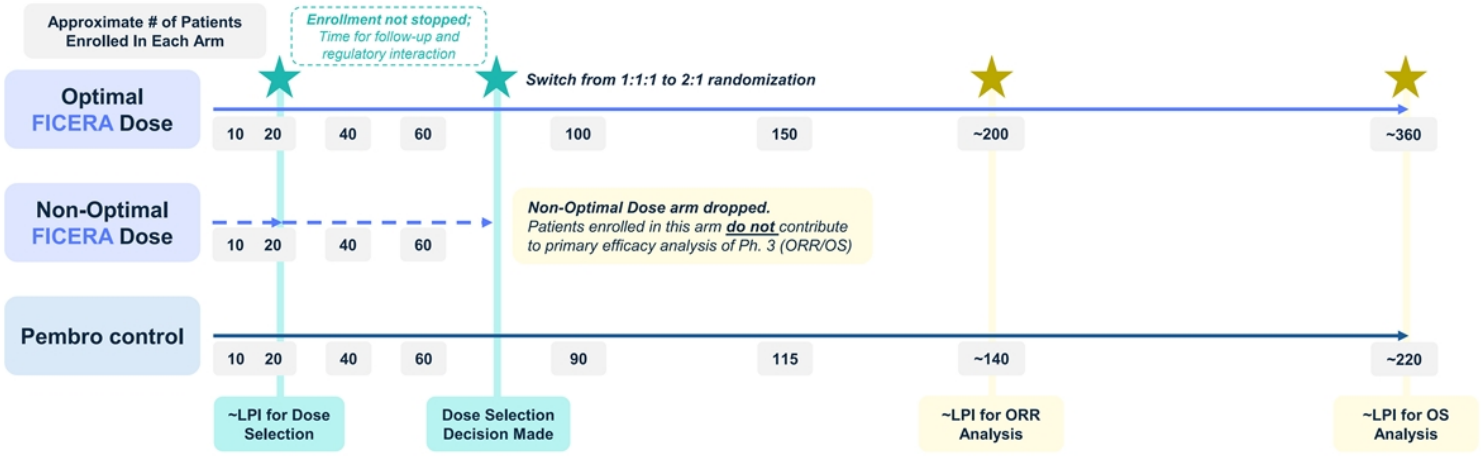
Design	Total Sample Size
Interim Analysis 1 (Dose Optimization)	n ~ 60
Interim Analysis 2 (ORR)	n ~ 415
Primary Analysis (OS)	n ~ 650

Anticipated data availability are based on current expectations and may be subject to delay.

FORTIFI-HN01

Seamless design in FORTIFI-HN01 expedites timelines to potential approval

Ph. 2/3 FORTIFI-HN01 is designed such that patients enrolled in dose selection at the optimal dose will contribute to the final efficacy analyses, while those at the non-optimal dose will not



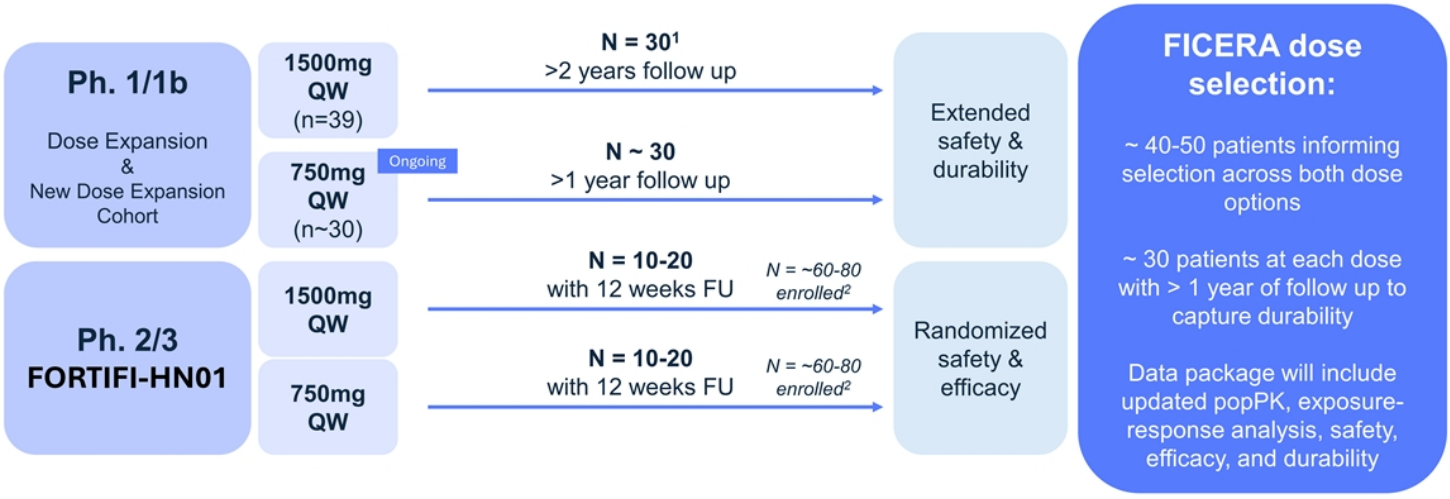
1. Dose selection will be made after the first ~10-20 patients in each dose arm have at least 12-weeks of follow up. At the time of dose selection, it is estimated that ~60-100 patients in each dose arm will have been enrolled in the non-optimal dose arm and will not contribute to the efficacy analyses of the Ph. 3 trial.

LPI = last patient in.

Dose Selection

Proposed OBD data package will include data from both Ph1b and Ph2/3 studies

Based on FDA feedback, team will request a Type D meeting to seek agreement on the dose to carry forward



1. In Ph. 1/1b dose expansion, of the n=42 patients across HPV-negative and HPV-positive, the n=30 HPV-negative patients will inform dose selection.
2. Dose selection will be made after the first ~10-20 patients in each dose arm have at least 12 weeks of follow up. At the time of dose selection, it is estimated that ~60-80 patients in each dose arm will have been enrolled, and thus those patients in the non-optimal dose arm will not contribute to the efficacy analyses of the trial.
Anticipated data availability are based on current expectations and may be subject to delay.

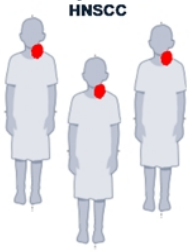
OBD = optimal biological dose. FU = follow up. PopPK = population pharmacokinetics.

LA HNSCC Opportunity

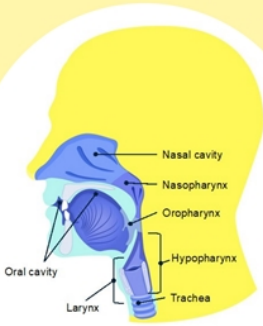
Advancing to earlier stages of HNSCC represents a significant opportunity for FICERA

>60K cases / year in U.S.

Locally advanced HNSCC



Recurrent / Metastatic HNSCC



expansion opportunity

LA HNSCC → **Relapse**

50% Relapse within 2 years after treatment for LA HNSCC[1]

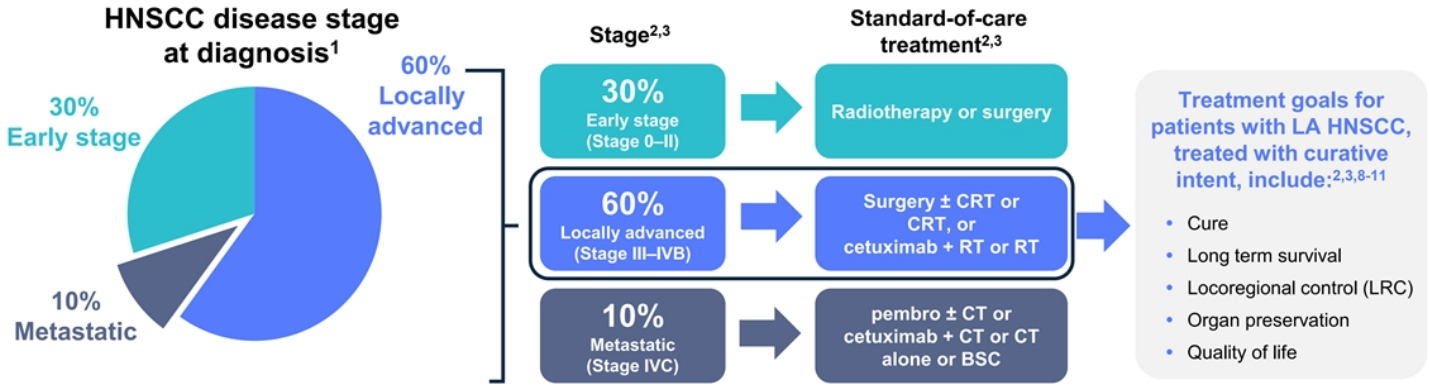
Metastatic at diagnosis → **1L R/M HNSCC**

CPS = 0	**CPS≥1**
Platinum-based + cetuximab	**Pembrolizumab mono**
Study	Platinum + 5FU + Pembro[2]
	Study

LA HNSCC Opportunity

Most HNSCC patients are diagnosed with locally advanced (LA) HNSCC

*Strong rationale to explore **FICERA** in LA-HNSCC*



FICERA has strong biologic rationale to deliver on treatment goals of LA HNSCC

1) **Targeting TGF-β in LA setting:** radiation therapy associated with increases in TGF-β[12]; target resistance early and reduce scarring / fibrosis in normal tissue for organ preservation and improved quality of life
2) **Cetuximab precedent** in combination with RT for unresectable, cisplatin-ineligible patients; improve long-term survival and LRC

1. Corvò R. Radiother Oncol. 2007 Oct;85(1):156-70; 2. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers V3.2021; 3. Machiels JP, et al. Ann Oncol 2020;31:1462–1475; 4. Bray FF, Pisani P, Parkin DM. GLOBOCAN 2002: Cancer Incidence, Mortality and Prevalence Worldwide. IARC Cancer Base No. 5. version 2.0. Lyon: IARC Press; 2004. http://www-dep.iarc.fr; 5. Seiwert et al. Nature Clinical Practice Oncology, March 2007; Vol 4 No. 3 (The chemoradiation paradigm in head and neck cancer); 6. Bernier J, et al. N Engl J Med 2004;350:1945–1952; 7. Cooper JS, et al. N Engl J Med 2004;350:1937–1944; 8. Lo Nigro C, et al. Cancer Manag Res 2017;9:363–371; 9. Ang KK. Oncologist 2008;13:899–910; 10. Haigentz M Jr, et al. Expert Opin Pharmacother 2010;11:1305–1316; 11. Haddad RI, et al. Ann Oncol 2018;29:1130–1140; 12. Centurione, L., et al. (2016). Frontiers in Oncology, 6, 175

Beyond HNSCC

Plan to expand FICERA to additional tumor types where there is strong biologic rationale and / or early signals of activity

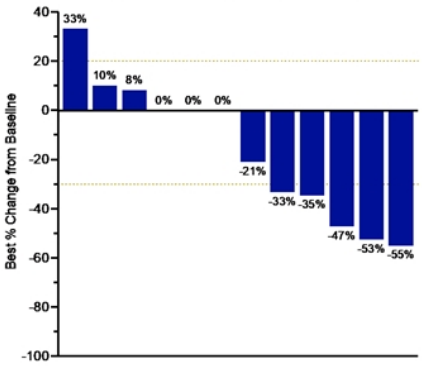
Other Solid Tumors / Squamous Cell Carcinomas

Potential expansion to areas of EGFR / TGF-β involvement:

- **Cutaneous squamous cell carcinoma (cSCC)** – preliminary 42% ORR (5/12) in 2L+ PD-1-refractory with **FICERA monotherapy**
- **Colorectal cancer (CRC)** – cetuximab precedent
- **Squamous cancer of the anal canal (SCAC)** – **data to be presented at a medical meeting in Q1 2025**

cutaneous SCC (cSCC)

FICERA monotherapy: 42% ORR across n=12 patients in 2L+ post-PD-1



CRC

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

Expansion to mCRC

- **EGFR an established target** in mCRC
- Ability to **target TGF-β driven resistance** to EGFR targeted therapies
- Initial late-line development strategy supported by clinical evidence[1] of **activity of EGFR-rechallenge in wtRAS CRC** population
- Rationale to **combine TGF-β inhibition with immunotherapy** to address overlapping but non-redundant tumor survival mechanisms

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 in Stage 1
- **FICERA** + pembro
  N = ~20 in Stage 1

Primary goals: *evaluate safety, tolerability, and initial efficacy (ORR/DCR). Potential to expand cohorts to n~50 in each arm in Stage 2.*

1. Sartore-Bianchi, Andrea, et al. Nature Medicine 28.8 (2022):

At a Glance

Bicara Therapeutics is poised to establish FICERA + pembro as a new potential therapy for 1L HPV-negative R/M HNSCC

Focus	Key Achievements
Clinical	✓ Showed strong clinical activity of FICERA in combination with pembro in **HPV-negative** 1L R/M HNSCC **(64% ORR, 18% CRR, 9.8mos PFS)** ✓ Demonstrated activity of FICERA in other squamous cell carcinomas and solid tumors
Regulatory	✓ Aligned on registration-enabling Ph. 2/3 trial design and established a clear path to FDA approval based on OS, with potential for an accelerated approval upon an interim analysis based on ORR
FORTIFI-HN01	✓ Initiated FORTIFI-HN01, a pivotal Ph. 2/3 trial in **HPV-negative** 1L R/M HNSCC in December 2024
Financial	✓ Robust financial position with ~$521M in cash and cash equivalents[1], including ~$362M in gross proceeds from upsized IPO

1. Cash and cash equivalents as of 9/30/24.