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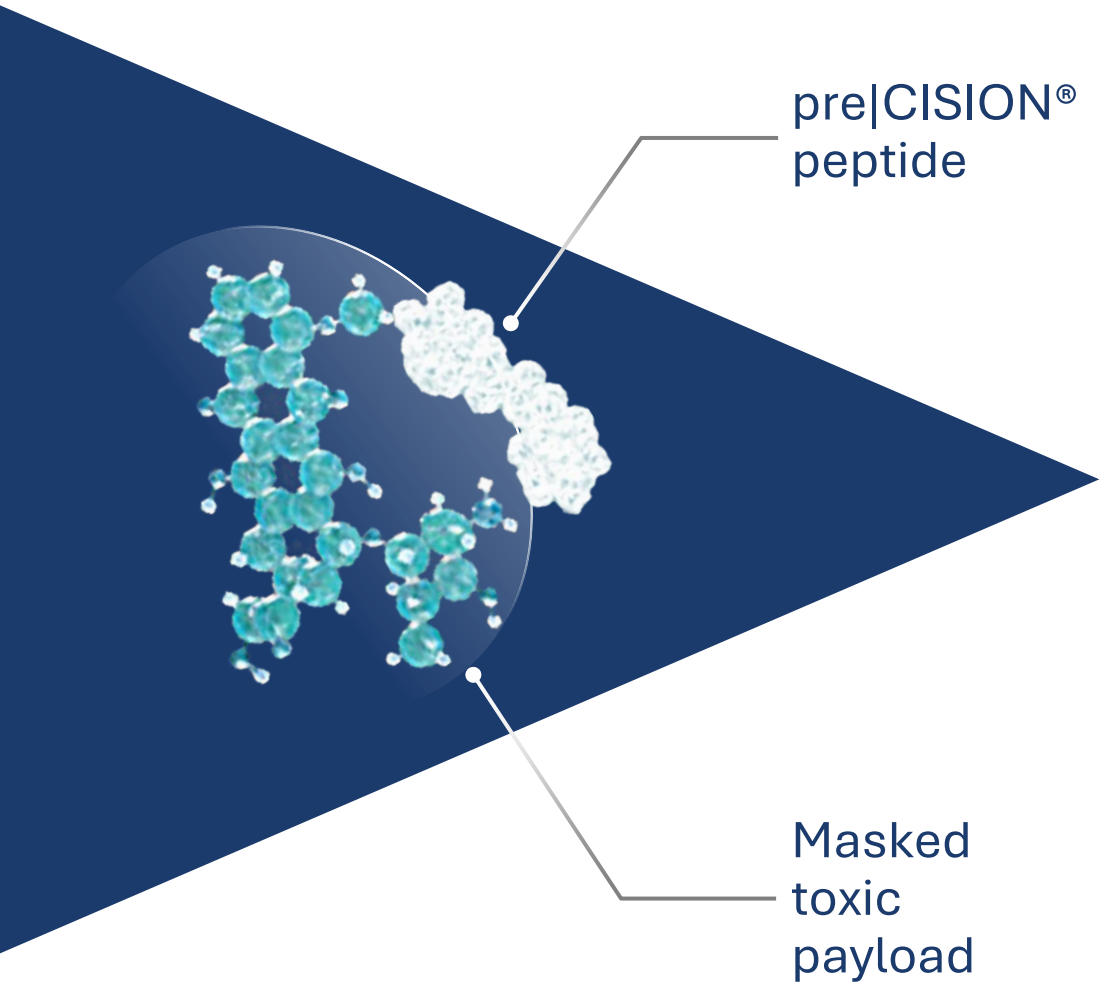
pre|CISION Update: Faridoxorubicin Phase 1b Data in Patients with Salivary Gland Cancers

December 2025

pre|CISION®: FAP-Activated Drug Delivery Platform



Silent in the bloodstream.
Active in the tumor.

Drug release is triggered *ONLY* at the tumor site by FAP, a protein found in tumor-supporting cells

FAP: Fibroblast activation protein

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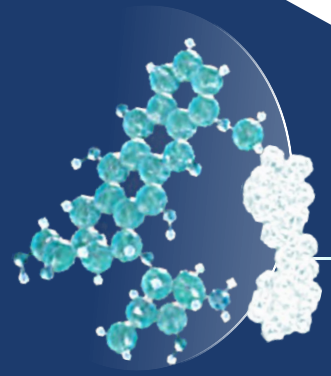
The pre|CISION® Peptide Masks the Toxic Effects of Cancer Drugs and Releases the Active Drug Directly in the Tumor



pre|CISION®
peptide

MASKED
Toxic payload

Masks the toxic effects of a payload in the tissues

Tumor-specific payload release with the FAP enzyme via the bystander effect

Enhances the tumor exposure of payload while limiting the blood exposure

Enables prolonged treatment beyond that permitted with conventional therapy which translates to enhanced survival

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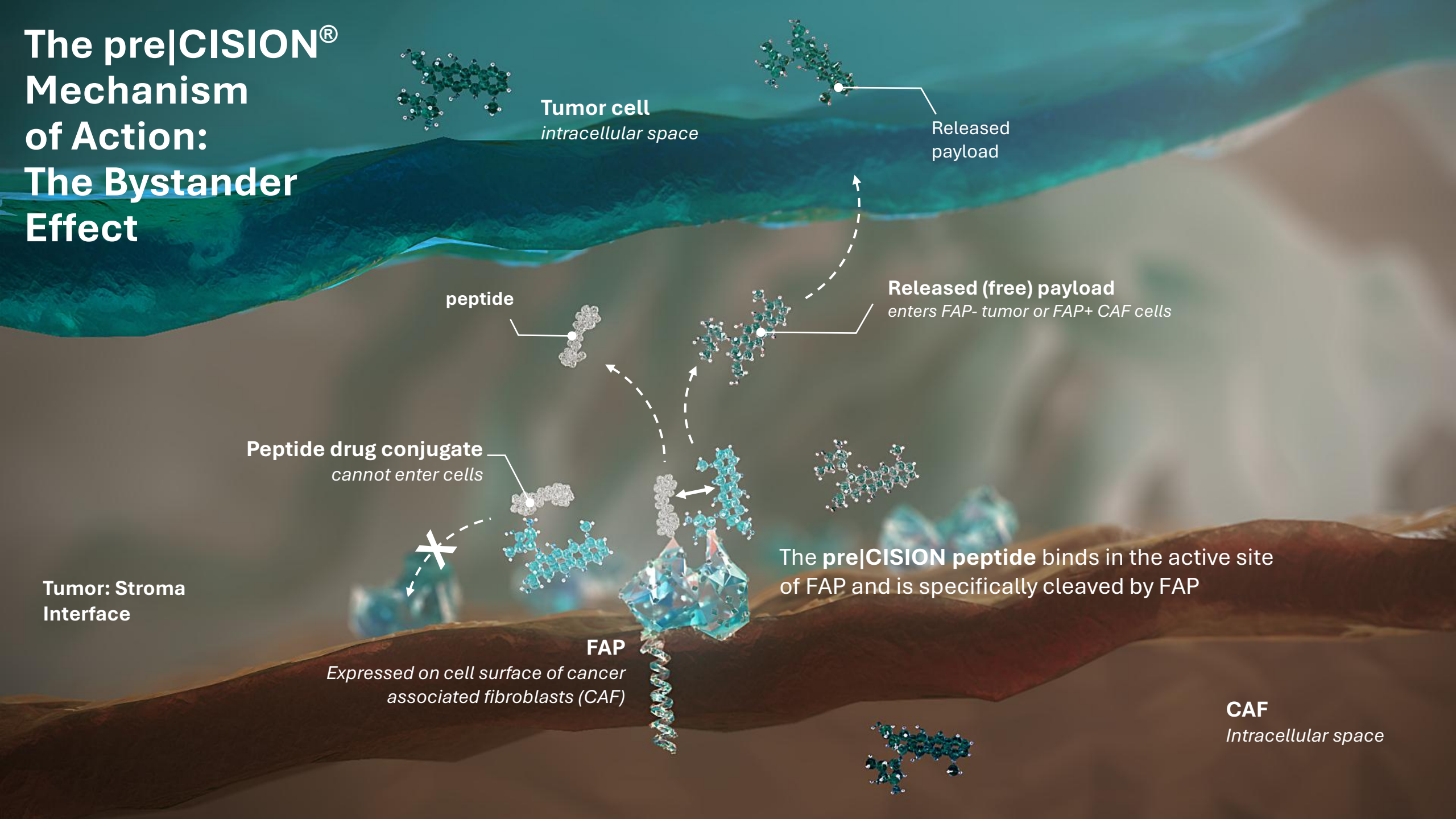
The pre|CISION® Mechanism of Action: The Bystander Effect



FAP-Dox (AVA6000): Phase 1 Trial Delivers 4 Key Findings

FAP-Dox eliminates the severe cardiac toxicity of doxorubicin

6-20% cardiac tox v. 0%

Dramatically reduces hematologic and GI toxicities of doxorubicin

Limited severe neutropenia

Concentrates released doxorubicin in the tumor 100-fold over plasma

100:1 tumor concentration

Evidence of preliminary activity in salivary gland cancer and sarcoma

Encouraging activity

Phase 1 Trial shows benefits over conventional doxorubicin

Faridoxorubicin Phase 1b data (FAP-Dox, AVA6000)

Preliminary Data in the Expansion Cohort Enrolling Patients with Salivary Gland Cancers

Salivary Gland Cancers (SGC): The Indication

INCIDENCE

Salivary gland cancer is rare

~3 cases/100,000 people in the Western world annually

INCIDENCE

This translates to approximately **2,000 to 2,500 new cases each year** in the US, making up **6% to 8% of all head and neck cancers**

TREATMENT

There is no standard of care treatment regimen for advanced disease

that is defined in the global recommendations*

TREATMENT

A subset of SGC patients receive targeted therapy^

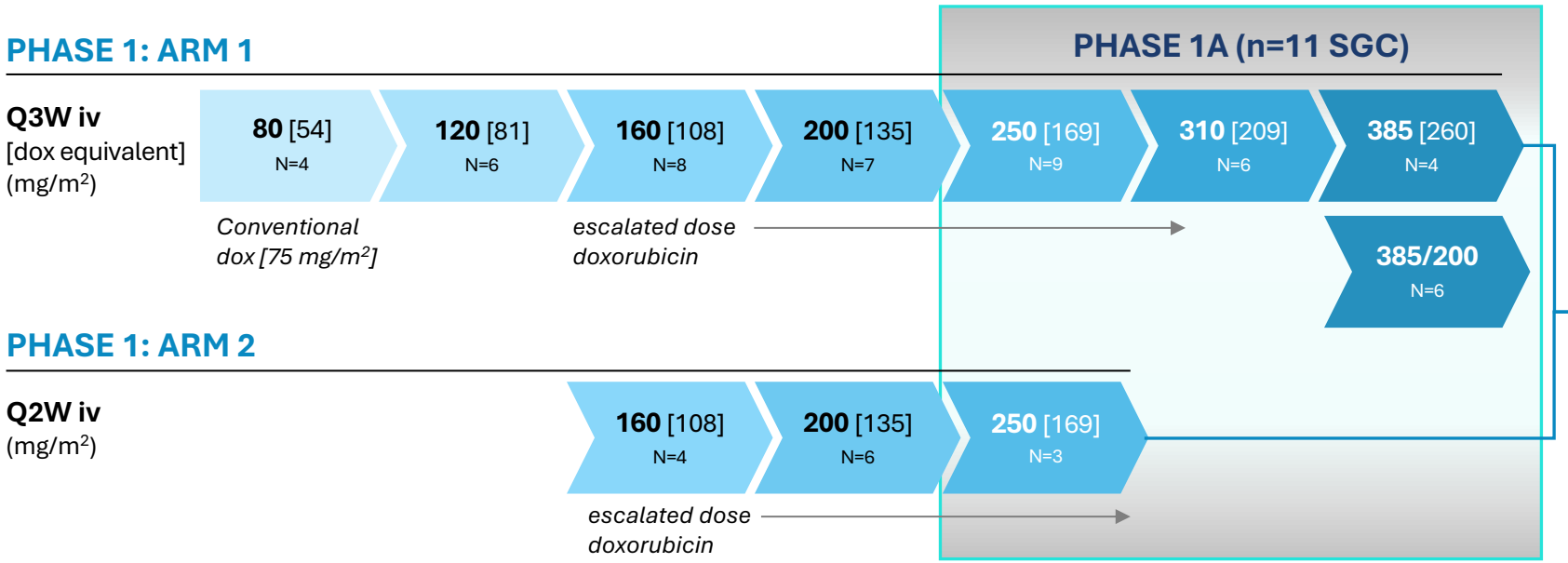
with the expression of HER2 or Androgen Receptor

FARIDOXORUBICIN
IS AIMED TO BECOME **THE STANDARD OF CARE**
in the first or second line setting in advanced or metastatic disease

*e.g. NCCN preferred regimen is “None”.
^Her2-directed therapy in patients with Her2+ cancers or Androgen Deprivation Therapy (ADT) in patients with Androgen Receptor (AR)+ cancers

Faridoxorubicin Phase 1 Trial Design and Patient Population

Phase I completed end 2024, Dose identified and expansion cohorts ongoing



PHASE 2

Recommended dose for expansion (RDE)
(mg/m²)

PHASE 1B (n=19 SGC)

EXPANSION COHORTS

Triple Negative Breast Cancer
PD-L1-negative, BRC*Awt*

High-grade Soft Tissue Sarcoma
(UPS, DDLPS, 1L/2L)

Salivary Gland Cancer
(SGC), any histology, 1L/2L

PHASE 1 DOSE ESCALATION: PATIENT POPULATION AND METHODS

Patients

FAP-positive cancers including:

- Sarcoma
- Pancreatic
- Colorectal
- Head & neck

Expression levels

- FAP-high (uniform expression)
- FAP-mid (heterogeneous)

Anthracycline limits

- Prior ≤350 mg/m²
- Trial max ≤550 mg/m²

Primary Endpoint

- Safety (primary)

Secondary Endpoint

- Efficacy by FAP level (secondary)

The Baseline Characteristics of SGC Patients in Phase 1b are Similar to the Phase 1a Population

	SGC Ph Ib N=22[1]
Age, median (range)	63 (32-81)
Sex, m/f, n (%)	12 / 10 (55 / 45)
ECOG, 0/1, n (%)[2]	15 / 5 (58.2 / 22.7)[2]
Race	
White, n (%)	17 (77.3)
Asian, n (%)	2 (9.1)
Black or African American, n (%)	3 (13.6)
Ethnicity	
Hispanic/Latino, n (%)	1 (4.5)
Non-Hispanic, non-Latino, n (%)	20 (91)
Not reported/unknown, n (%)	1 (4.5)
Prior cancer therapy	
No. prior regimens (metastatic), median (range)[3]	1 (0-2)

Data cutoff 15 Oct 2025

[1] Ph Ib enrollment of 22 patients included 2 pts not eligible (ECOG) and 1 pt not evaluable for efficacy | [2] Two pts enrolled with EGOG 2 and were not eligible

[3] Fifteen pts with prior therapy, 7 pts enrolled in 1L setting

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The Safety Profile of Faridoxorubicin in the SGC Ph Ib Population is Consistent with Prior Reports

	Faridoxorubicin All Gr 3-4 Events N=22[1]
Neutropenia, n (%)	3 (13.6)
Lymphopenia, n (%)	2 (9.1)
Fatigue, n (%)	2 (9.1)

Data cutoff 15 Oct 2025

[1] Ph Ib enrollment of 22 patients are all evaluable for safety, two events of decreased neutrophils and decreased lymphocytes were added to total

No Grade 3 or 4 cardiac adverse events were reported in the Ph Ib cohort

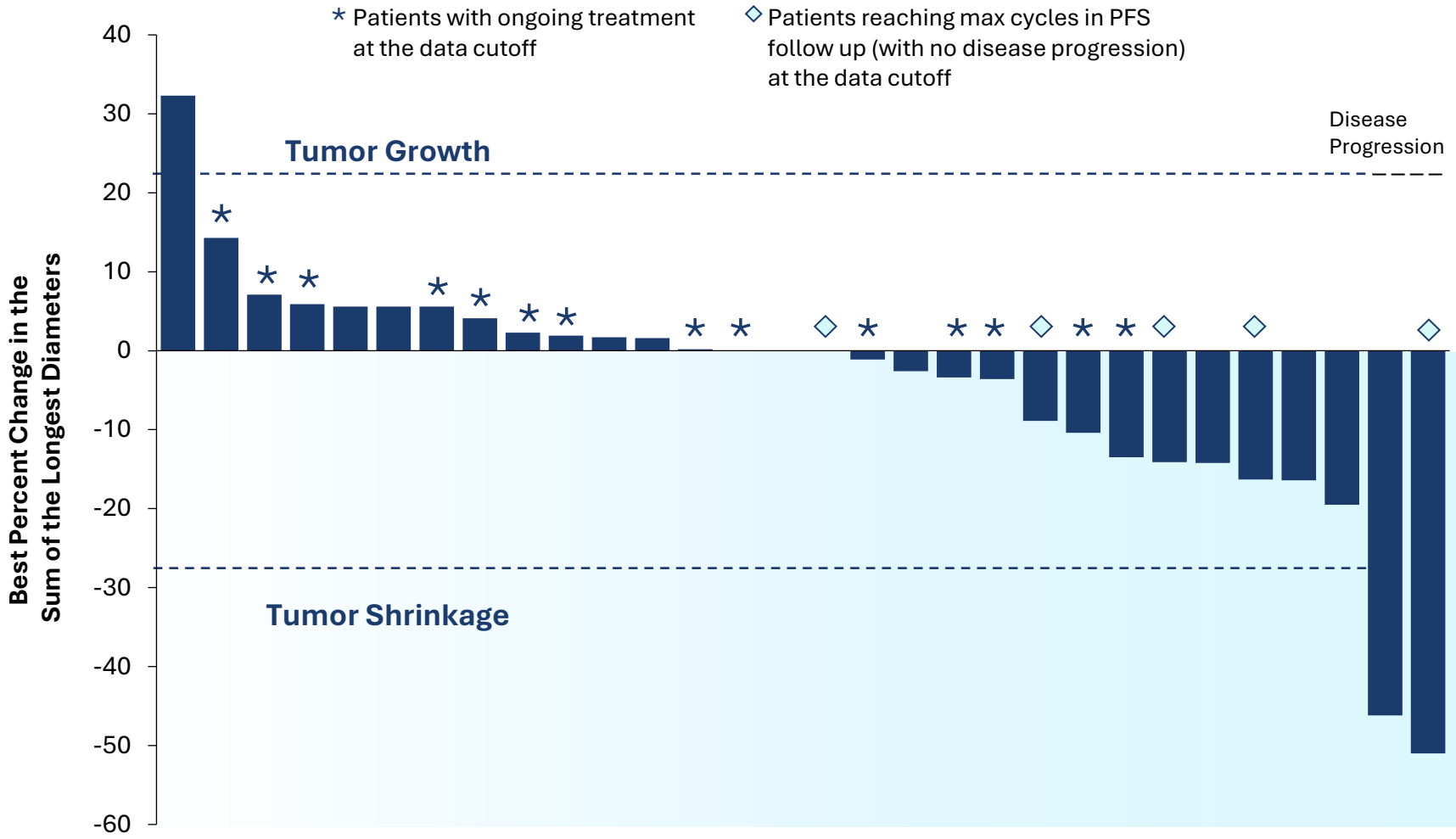
	Faridoxorubicin ≤450 mg/m^2 N=18	Faridoxorubicin 550 mg/m^2 N=4[1]
LVEF decreases observed[1]		
LVEF ≥ LLN and LVEF reduced >20%	0	0
LVEF < LLN and LVEF reduced >10%	0	0

Data cutoff 15 Oct 2025

[1] Four pts have reached max cycles at 550 mg/m2 in the ongoing Ph Ib

Grade 1-2 cardiac AE reported in 1 pt of QT prolongation

Faridoxorubicin: Durable Tumor Shrinkage in Patients with Salivary Gland Cancers Across Phase 1a and Phase 1b



Best Overall Response (n=30)

	PHASE 1a/1b N=30
Partial response, n	2
Minor response[1], n	7
Progressive Disease	3
Stable disease[1], n	25
Median PFS[2]	*Not reached*

Multiple responders in the trial with durable tumor shrinkage

90%

disease control rate
in an indication that is reported to be chemorefractory

Combined Phase 1a and 1b patient population in the AVA6000 trial. Data cutoff 15 September 2025 (Phase 1a), 15 October 2025 (Phase 1b)
All pts with the diagnosis of salivary gland cancer treated at or above the 250 mg/m2 dose level, regardless of schedule *Phase 1a) or 310 mg/m2 Q2W *Phase 1b).
1 Minor responses defined as best tumor response per RECIST v1.1 of 10-29% tumor shrinkage, partial response >30% tumor shrinkage. Patients with minor responses are considered stable disease per RECIST v1.1.
[2] Median PFS not reached with 14/30 pts ongoing in treatment and 5/30 pts ongoing in PFS follow-up

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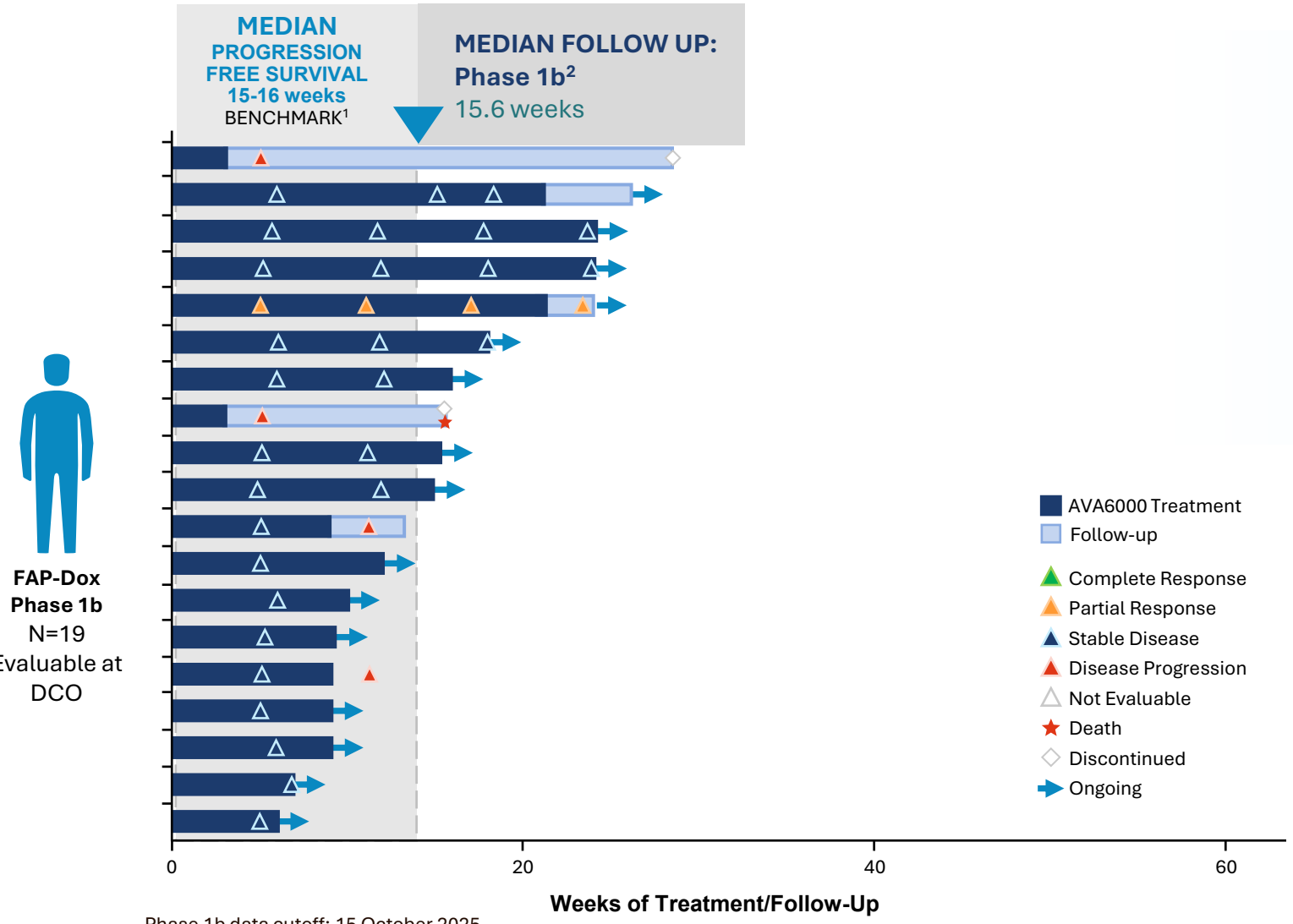
Phase 1b: Median PFS Has Not Been Reached in Patients with Salivary Gland Cancers



"FAP-Dox would completely become standard of care for Adenoid Cystic Carcinoma (ACC), your comparator is lenvatinib which has 12% ORR and horrible toxicity … "

Consultant in Medical Oncology
NHS Foundation Trust[3]

" … I'd use this very widely in 2L+ for patients who hadn't received it yet… **there's no approved therapy in this space and with this data there's no reason not to prescribe this … "**

Professor of Clinical Medicine
UCSF[3]

Phase 1b data cutoff: 15 October 2025

[1] Licitra et al. ESMO 2024

[2] Median Follow Up is calculated using the Reverse Kaplan Meier Method and median among 19 evaluable patients is reported

[3] LEK Consulting SGC CDP and commercial analysis

Faridoxorubicin Phase 1b data (FAP-Dox, AVA6000)

Translational Science Program

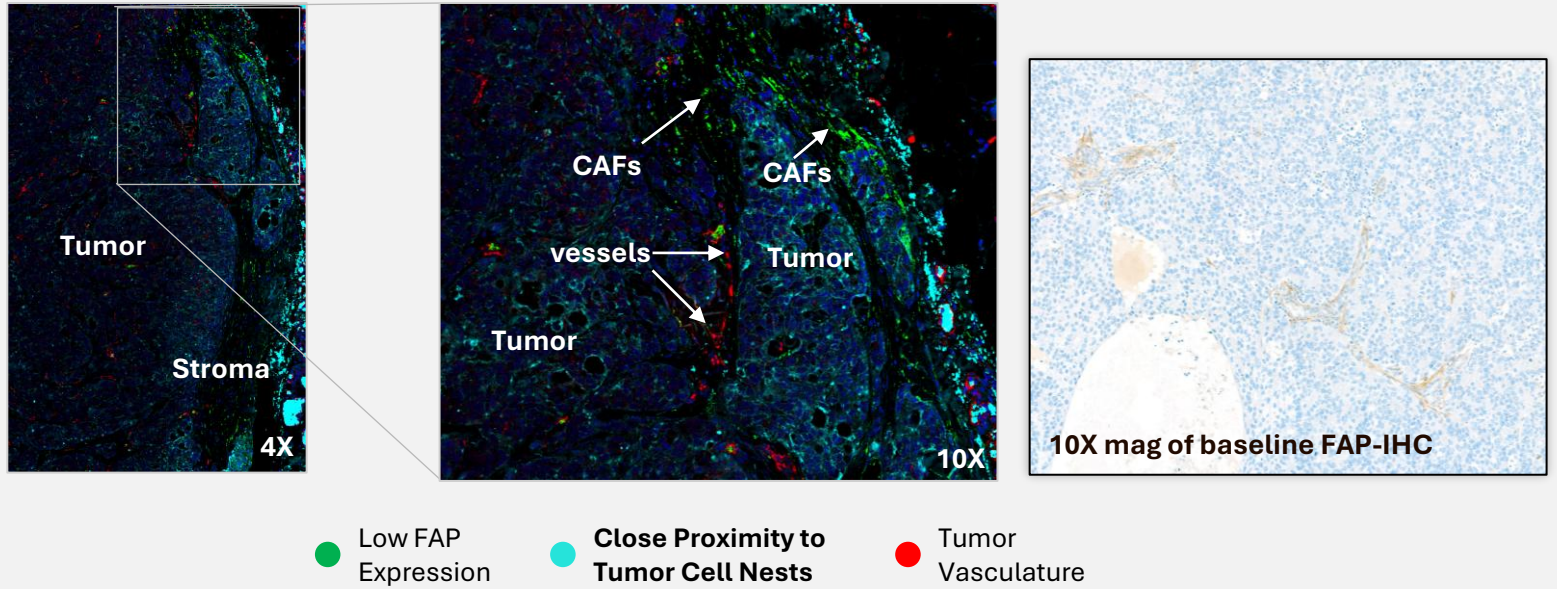
Recent Case of a Minor Response in a Patient with Adenoid Cystic Carcinoma Receiving Faridoxorubicin

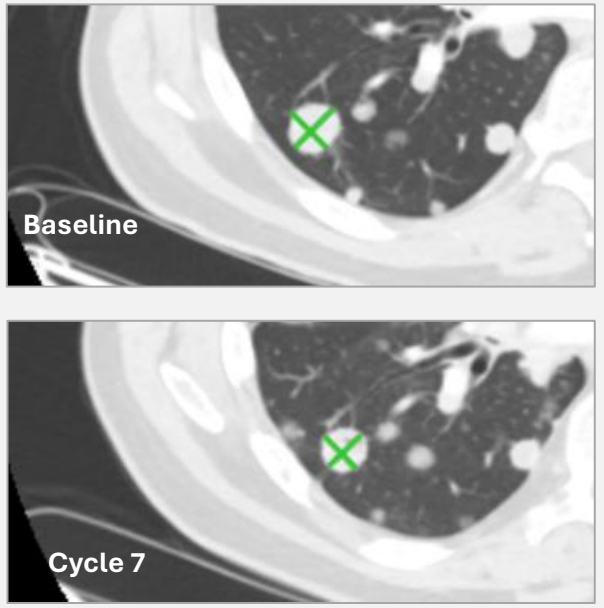
CASE STUDY

52 yo male with diagnosis of high-grade adenoid cystic carcinoma (ACC) of the right parotid salivary gland

- Patient received surgery and radiotherapy to treat local disease at diagnosis
- Enrolled in the faridoxorubicin trial (June 2025) and is receiving 310 mg/m^2 Q3W
- Patient is FAP-positive in cancer-associated fibroblasts (CAF), but limited expression (1+)

Minor response observed in target lesions at 3rd 6-week scan





Avacta, unpublished data

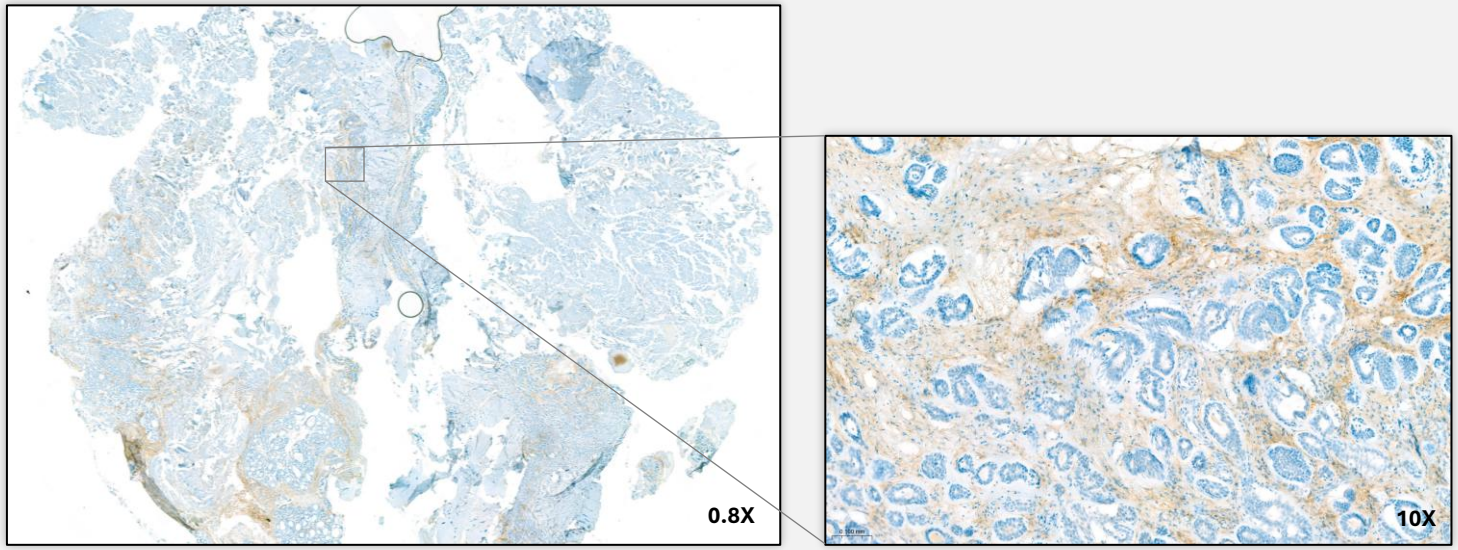
FAP-Dox: Recent Case of a Minor Response in a Patient with Adenoid Cystic Carcinoma

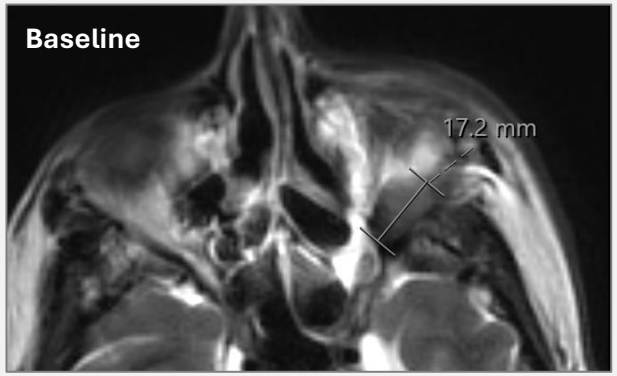
CASE STUDY

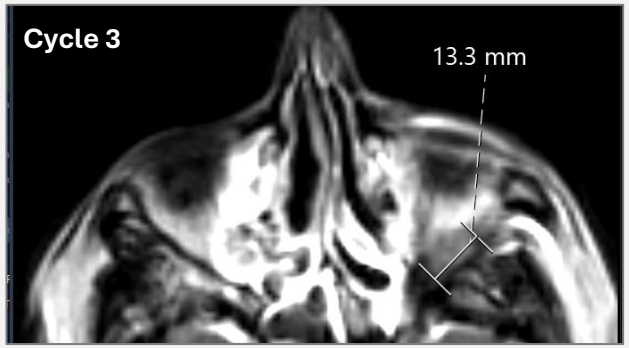
52 yo female with diagnosis of recurrent adenoid cystic carcinoma of the left maxilla

- Patient received surgery and radiotherapy to treat disease
- Enrolled in the AVA6000 trial (August 2025) and is receiving 310 mg/m^2 Q3W
- The patient has **high FAP expression** throughout the tumor tissue in cancer-associated fibroblasts (CAF) surrounding tumor cells

Rapid, Minor response observed in target lesions at 2nd scan

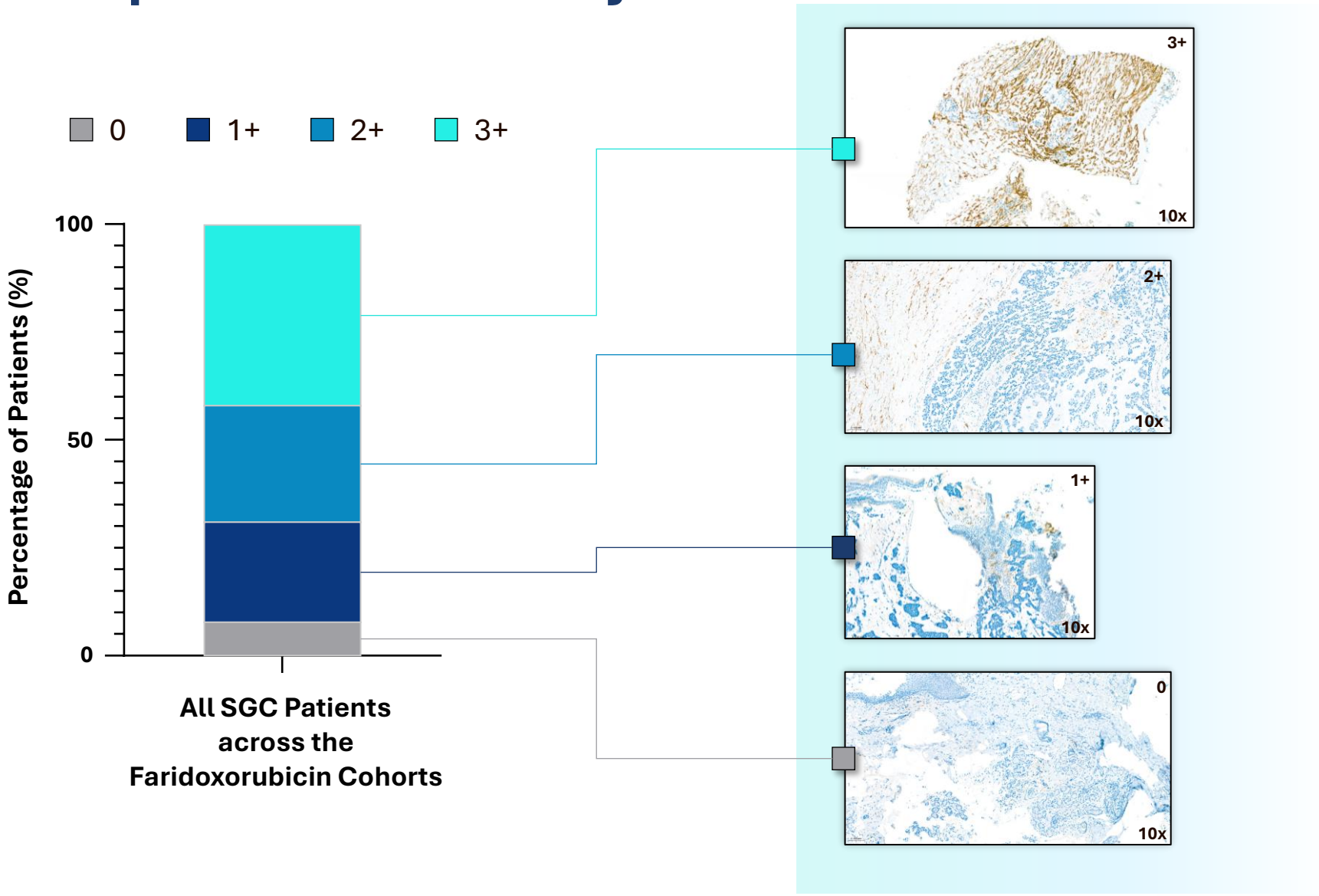






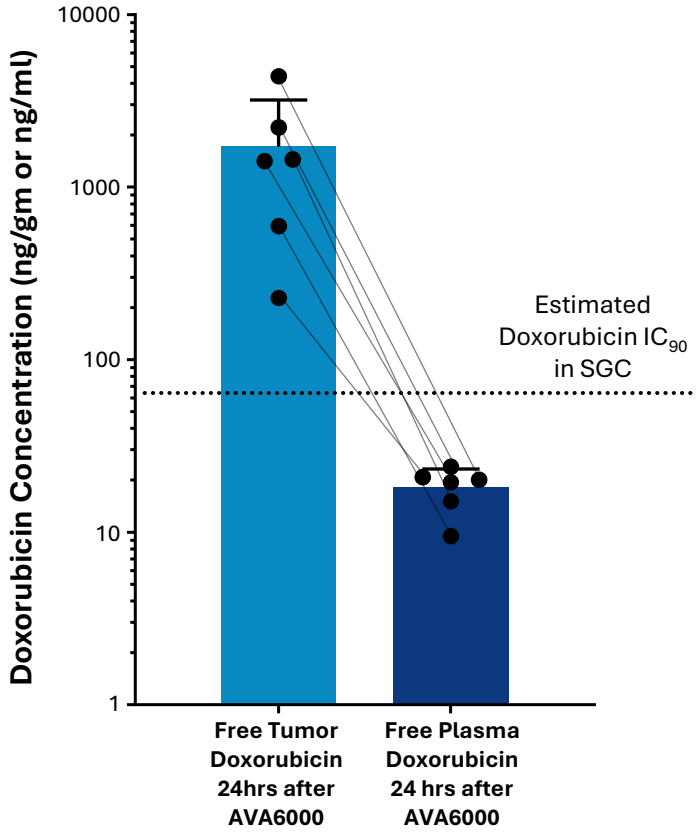
Avacta, unpublished data

The Majority of Patients Treated in the SGC Indication Demonstrate High Levels of Expression of FAP by IHC

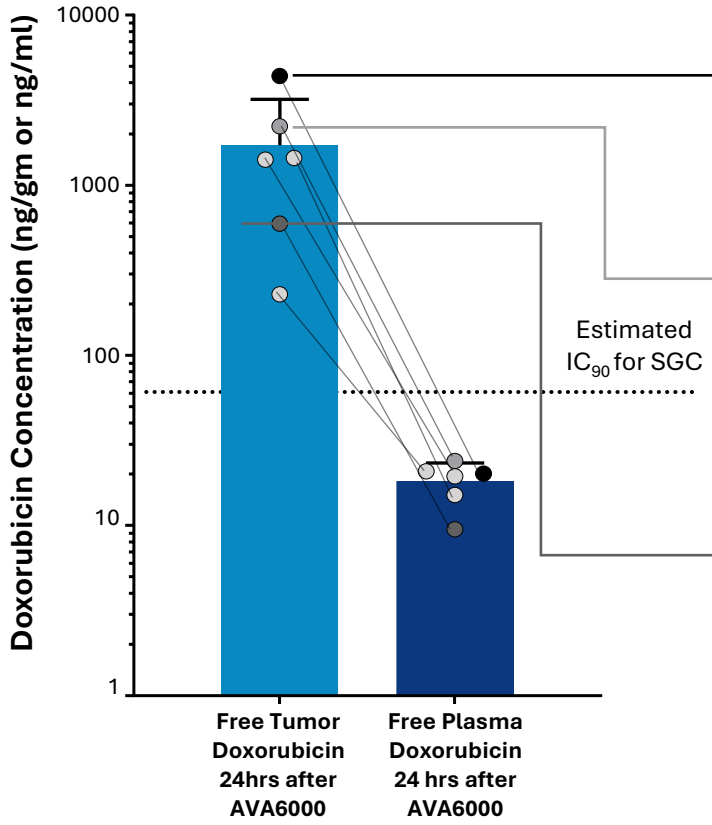


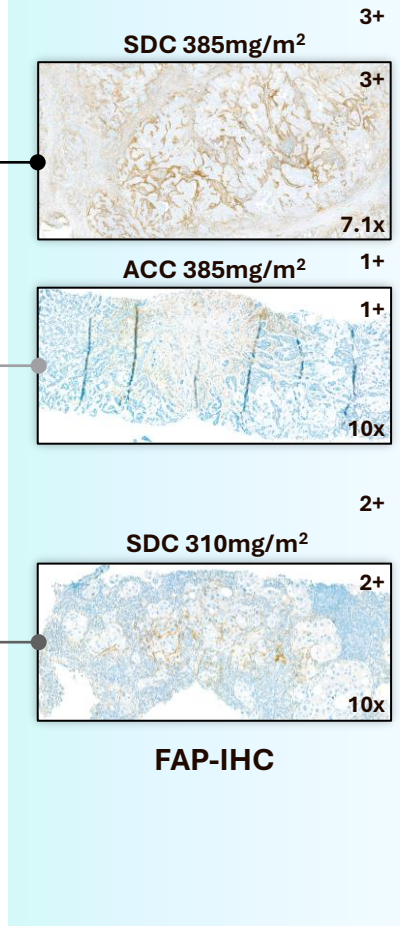
Effective Concentration of Doxorubicin is Observed Regardless of Expression Level of FAP in Patients with Salivary Gland Cancer

Doxorubicin tumor and plasma concentrations 24 hours post AVA6000 dose in SGC pts only

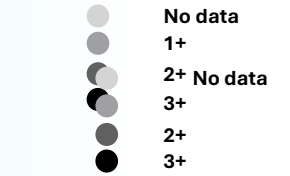


Doxorubicin tumor and plasma concentrations 24 hours post AVA6000 dose in SGC pts





Tumor FAP-IHC Score



- Tumor biopsies and plasma samples were obtained 24 hours after the 1st dose of AVA6000 and analyzed for Doxorubicin concentrations
- These doxorubicin levels at 24 hours were compared to matched plasma samples
- Free doxorubicin concentrations were quantified by LC-MS/MS
- Tumor FAP expression was assessed by immuno-histochemistry and scored using a 0-3+ scale based on staining intensity and FAP+ area
- Dots indicate individual patient samples with line interconnecting matched plasma
- Colors of the dots indicate tumor FAP enzymatic activity

KEY Takeaways

Faridoxorubicin in SGC in Ph Ib

Safety profile of faridoxorubicin is consistent in the Ph Ib in patients with SGC
Dramatic reductions in hematologic toxicities are observed in this preliminary data set along with no severe cardiactoxicity, which is consistent with the reports in the Phase 1a

The preliminary efficacy observed in the Phase 1b portion of the trial is highly encouraging
Similar results are observed in this indication as reported in the Phase 1a with a disease control rate of 90% maintained in the 30 patients evaluable, tumor shrinkage observed

Release of doxorubicin is observed and tumor shrinkage noted to low levels of FAP
Robust tumor shrinkage noted even at the level of 1+ IHC expression of FAP in the tumor microenvironment

Released doxorubicin levels in the tumor biopsy exceed the IC90 concentration for SGC
Release of doxorubicin across patients with SGC is observed at levels that exceed preclinical derivation of concentrations needed for optimal killing of SGC cells

Enrollment continues in the Phase 1b portion of the trial
Enrollment continues and further data updates are planned for this portion of the Phase 1b trial of faridoxorubicin

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