

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): September 09, 2026

Pyxis Oncology, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40881
(Commission File Number)

83-1160910
(IRS Employer
Identification No.)

321 Harrison Avenue
Boston, Massachusetts
(Address of Principal Executive Offices)

02118
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 453-3596

(Former Name or Former Address, if Changed Since Last Report)

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(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	PYXS	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

On September 9, 2026, Pyxis Oncology, Inc. (the “Company”) provided a corporate update and issued a press release announcing updated data from its ongoing global Phase 1 monotherapy study of micvotabart pelidotin (MICVO) in patients with second-line and beyond recurrent/metastatic head and neck squamous cell carcinoma. A copy of the press release is attached as Exhibit 99.1 and the corporate presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K.

The information furnished under Item 7.01, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

The Company today announced updated data from its ongoing global Phase 1 monotherapy study evaluating micvotabart pelidotin (MICVO) in patients with second-line and beyond (2L+) recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC). The cutoff date for all data reported below is August 18, 2026.

Demographics

Table 1: Patient Demographics and Disease Characteristics – 5.4 mg/kg Dose Cap Population (N=35)

2L+ R/M HNSCC	5.4 mg/kg Dose Cap (N=35)	2L+ R/M HNSCC	5.4 mg/kg Dose Cap (N=35)
Race, n (%)		Primary Cancer Site, n (%)	
White	29 (82.9%)	Oropharynx	22 (62.9%)
Black or African American	2 (5.7%)	Oral cavity	6 (17.1%)
Asian	1 (2.9%)	Larynx	7 (20.0%)
Native Hawaiian or Other	1 (2.9%)	HPV Status (local)	
Not reported/Unknown	2 (5.7%)	HPV+ Oropharyngeal SCC, n (%)	18 (51.4%)
Age (years)		HPV-Unrelated, n (%)	17 (48.6%)
Median (min-max)	65 (41-74)	Prior Systemic Therapy, Median Lines (min-max)	3 (1-5)
Baseline weight (kg)		Prior Systemic Therapy in R/M Setting, Median Lines (min-max)	2 (1-4)
Median (min-max)	66.8 (47.8-99.2)	Taxane, n (%)	25 (71.4%)
Calculated BMI (kg/m2)		Platinum, n (%)	35 (100.0%)
Median (min-max)	22.4 (18.8-31.3)	Anti-PD-(L)1 Agent, n (%)	35 (100.0%)
Gender, n (%)		EGFRi, n (%)	20 (57.1%)
Male	29 (82.9%)	Cetuximab ¹	15
Female	6 (17.1%)	Petosemtamab ¹	3
Baseline ECOG Performance Status, n (%)		Ficerafusp alpha ¹	2
0	12 (34.3%)		
1	23 (65.7%)		

Data as of 18-Aug-2026

1. cetuximab: Eli Lilly and Company & Merck KGaA; petosemtamab: Genmab A/S; ficerafusp alpha: Bicara Therapeutics

Abbreviations: HPV: human papillomavirus; SCC: squamous cell carcinoma; EGFR: epidermal growth factor receptor; IO: immuno-oncology; ECOG: Eastern Cooperative Oncology Group; BMI: body mass index; PR: partial response; N/n: number of patients.

Efficacy Data

Table 2: Efficacy Data Summary – 5.4 mg/kg Dose Cap Efficacy-Evaluable Population (N=33)

Efficacy Measure	5.4 mg/kg Dose Cap (N=33)
Confirmed objective response rate (cORR), % (n/N)	36% (12/33)
Disease control rate (DCR), % (n/N)	94% (31/33)
Responders achieving response by the first scan at six weeks, %	75%
Responders achieving >50% tumor reduction from baseline*, %	83%
Median progression-free survival (mPFS), months, (95% CI)	6.2 (4.8 - 8.8)
12-month overall survival (OS) probability, %, (95% CI)	79% (58.1, 90.3)
Median overall survival (OS), months	NR (NR-NR)

Data as of 18-Aug-2026

*Per RECIST v1.1

Abbreviations: n/N: number of patients.

Table 3: Efficacy Data Across Key Patient Subgroups

Patient Subgroup	N	5.4 mg/kg Dose Cap Confirmed ORR, %	5.4 mg/kg Dose Cap Median PFS, months
HPV Status			
HPV+ oropharyngeal	17	35%	6.2
HPV-unrelated	16	38%	5.9
Prior EGFRi			
Yes	18	28%	5.0
No	15	47%	8.8
Prior Novel EGFRi*			
Yes	5	40%	5.8
Prior Taxane			
Yes	23	35%	6.2
No	10	40%	4.9

Data as of 18-Aug-2026
*Prior novel EGFRi subgroup is a subset of patients with prior EGFRi treatment.
Abbreviations: HPV: human papillomavirus; ORR: objective response rate; EGFRi: EGFR inhibitor; n/N: number of patients.

Safety Data
No new safety signals were observed with MICVO. The tolerability data was consistent with that of other ADCs with auristatin payloads and was generally manageable. Adverse events of interest, including peripheral neuropathy, generally occurred after patients had received evidence of benefit, and after prolonged duration of treatment.

Table 4: Safety Data Summary – 5.4 mg/kg Dose Cap Population (N=35)

TRAEs	5.4 mg/kg with Dose Cap (N=35)	
Treatment duration – median days (range)	120 (21-470)	
All TRAEs, n (%)	32 (91.4%)	
TRAEs of CTCAE Grade ≥ 3, n (%)	19 (54.3%)	
Non-Hematologic TRAEs of CTCAE Grade ≥ 3, n (%)	15 (42.9%)	
Serious TRAEs, n (%)	5 (14.3%)	
TRAEs leading to treatment discontinuation*, n (%)	5 (14.3%)	
TRAEs leading to treatment discontinuation days, median (min-max)	162 (104-212)	
TRAEs leading to dose reduction, n (%)	14 (40.0%)	
Treatment related deaths (Grade 5)	0	
ADC Payload TRAEs of Interest	5.4 mg/kg with Dose Cap (N=35)	
	Gr1/2	Gr3
Cutaneous, n (%)	17 (48.6%)	2 (5.7%)
Peripheral Neuropathy, n (%)	14 (40.0%)	6 (17.1%)
Peripheral Neuropathy days to onset, median (min-max)	82 (3-157)	166 (85-197)
Ocular, n (%)	10 (28.6%)	2 (5.7%)
Pneumonitis, n (%)	4 (11.4%)	0

Data as of 18-Aug-2026
*TRAEs leading to discontinuation, N=1 Ocular, N=1 Muscle Weakness, N=3 Peripheral Neuropathy
Abbreviations: ADC: antibody-drug conjugate; TRAE: treatment-related adverse event; CTCAE: Common Terminology Criteria for Adverse Events; Gr: grade; N: number of patients.

This Current Report on Form 8-K contains forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Form 8-K, including without limitation statements regarding the Company’s plans to develop, manufacture and commercialize its product candidate, including micvotabart pelidotin (‘MICVO’); preliminary data, timing and progress of the Company’s ongoing clinical trials; the expected results of the Company’s clinical trials; the ability of preliminary, initial and topline clinical data to de-risk MICVO and be confirmed with clinical trial progression, including the safety, tolerability, and potential efficacy of MICVO; the potential differentiation, advantage or effectiveness of MICVO compared to other approved products or products in development; the dosage and treatment potential of MICVO; the size and future of the market; the plans and objectives of management, and the future results of operations and financial position of the Company, are forward-looking statements. These statements are neither promises nor guarantees, but are statements that involve known and unknown risks, uncertainties and other important factors that are in some cases beyond the Company’s control that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the risks inherent in drug research and development, the Company’s projected cash runway and potential needs for additional funding; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in or failure to obtain regulatory approvals; the Company’s reliance on third parties and collaborators to conduct clinical trials, manufacture its product candidate, and develop and commercialize its product candidate; and the Company’s ability to compete successfully against other drug candidate. Accordingly, investors should not rely upon forward-looking statements as predictions of future events. Except as required by applicable law, the Company undertakes no obligation to update publicly or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits	
Exhibit No.	Description
99.1	Press Release dated September 9, 2026.
99.2	Presentation dated September 9, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Pyxis Oncology, Inc.

Date: September 09, 2026

By: /s/ Jitendra Wadhane
Jitendra Wadhane
Principal Financial and Accounting Officer

Pyxis Oncology Announces Positive Updated Data from Phase 1 Monotherapy Study of Micvotabart Pelidotin (MICVO) in Second-Line and Beyond Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (2L+ R/M HNSCC)

MICVO demonstrated rapid and deep responses, with a 36% confirmed objective response rate (cORR) and 94% disease control rate (DCR), with clinical activity observed across HPV status and prior-treatment subgroups

Substantial survival outcomes include median progression-free survival (mPFS) of 6.2 months and 12-month overall survival (OS) probability of 79%, with clinical activity observed across HPV status and prior-treatment subgroups

No new safety signals observed; tolerability profile expected & consistent with prolonged auristatin exposure; dose capping reduced frequency and severity of adverse events in high body weight patients

MICVO potentially addresses significant unmet need in 2L+ R/M HNSCC, where evolving first-line treatment landscape is expected to create a demand for novel non-EGFRi treatment options

Data support advancement of MICVO into a pivotal program in 2L+ R/M HNSCC, with initiation of Phase 3 Headliner™ trial planned for mid-2027

Company to host webcast today at 7:30 a.m. ET

BOSTON, September 9, 2026 (GLOBE NEWSWIRE) — Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today announced positive updated data as of the August 18, 2026 data cutoff date from its ongoing global Phase 1 monotherapy study evaluating micvotabart pelidotin (MICVO) in patients with second-line and beyond (2L+) recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC).

The updated results represent a population (N=33 efficacy evaluable) dosed at 5.4 mg/kg intravenously once every three weeks with a dose equivalent to or below a dose cap. These data demonstrated rapid and deep responses, with a 36% confirmed objective response rate (cORR) and 94% disease control rate (DCR). Median progression-free survival (mPFS) was 6.2 months, and the 12-month overall survival (OS) probability was 79% while median OS (mOS) has not yet been reached. Clinical activity was observed across key patient subgroups, including HPV status and prior treatment. No new safety signals were observed (N=35 safety evaluable), and dose capping reduced the frequency and severity of adverse events in high body weight patients.

MICVO, the company's lead program, is a first-in-concept antibody-drug conjugate (ADC) targeting extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix. MICVO's differentiated, non-EGFR targeting mechanism of action positions it to potentially serve a significant patient population and address unmet need in 2L+ R/M HNSCC as the first-line treatment landscape continues to evolve.



“There remains significant need for effective treatment options for patients with recurrent or metastatic head and neck cancer who progress following first-line therapy, particularly as the front-line treatment landscape continues to evolve,” said Alan L. Ho, M.D., Ph.D., Chief, Head and Neck Oncology Service and Attending Medical Oncologist, Memorial Sloan Kettering Cancer Center. “In this heavily pretreated population, these results demonstrated rapid and deep responses, along with progression-free survival and preliminary overall survival results that warrant further evaluation.”

“These updated data reinforce our conviction in MICVO’s potential to become an important treatment option for patients with cancer,” said Tom Civik, Chief Executive Officer and Chairman of Pyxis Oncology. “We are particularly encouraged by the combination of rapid and deep responses, substantial survival outcomes and a manageable safety profile. The data also provide important validation of our dose capping strategy, which was intended to maintain clinical activity while mitigating the risk of safety events. Based on feedback from the FDA and EMA on the design of our pivotal Phase 3 study, Headliner™, we believe MICVO is well positioned for success in a randomized trial, which we plan to initiate in mid-2027.”

Updated MICVO Phase 1 Monotherapy Trial Results as of August 18, 2026

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Data as of 18-Aug-2026

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Abbreviations: ADC: antibody-drug conjugate; TRAE: treatment-related adverse event; CTCAE: Common Terminology Criteria for Adverse Events; Gr: grade; N: number of patients.

MICVO Next Steps

Monotherapy

Pyxis Oncology is advancing the clinical development of MICVO through Project Optimus, a U.S. Food and Drug Administration (FDA) initiative focused on dose optimization and dose selection in oncology drug development. An End of Phase 2 meeting with the FDA to align on dose selection is anticipated in the first quarter of 2027. Updated overall survival data from the MICVO monotherapy study are expected in the first half of 2027.

The Company has aligned with the feedback from the FDA and the European Medicines Agency (EMA) on the design of the planned pivotal Phase 3 monotherapy study of MICVO in patients with second- or third-line R/M HNSCC who have progressed following treatment with both a platinum-based therapy and an anti-PD-1 therapy. The randomized, open-label, 2-arm study will enroll approximately 500 patients who will be randomized 1:1 to receive MICVO or investigators' choice of cetuximab, docetaxel, or methotrexate. The co-primary endpoints of the study will be overall response rate and overall survival. Pyxis Oncology plans to initiate the study in mid-2027 following alignment with the FDA on dose selection.

Combination with KEYTRUDA® (pembrolizumab)

Pyxis Oncology expects to report updated data from the ongoing Phase 1/2 combination dose escalation study of MICVO and Merck's (known as MSD outside of the US and Canada) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) for 1L R/M HNSCC patients in the fourth quarter of 2026. Preliminary positive [results](#) for the treatment of 1L/2L+ R/M HNSCC were shared in December 2025. Additional data evaluating initial durability and selection of the recommended Phase 3 dose (RP3D) for the 1L combination are expected in the second half of 2027.



Webcast Information

Pyxis Oncology will host a live webcast today at 7:30 a.m. Eastern Time. To participate in the live event, please register using this link. The event and accompanying slides can be accessed by visiting the investor relations section of the Company's website at <https://ir.pyxisoncology.com>. An archived webcast will be available on the Company's website following the event.

About the MICVO Phase 1 Monotherapy Trial

The ongoing Phase 1 monotherapy study of MICVO is a multi-part study. Part 1 was a dose escalation study across multiple doses and tumor types, with initial results shared in November 2024. Part 2 is a dose expansion study in 2L+ R/M HNSCC. Preliminary Phase 1 study results in 2L+ R/M HNSCC were shared in December 2025.

The dose expansion portion of the study includes two arms: post-platinum and anti-PD-(L)1 patients (Arm 1) and post-EGFR inhibitor and anti-PD-(L)1 patients (Arm 2). Target enrollment for each arm was approximately 20 patients, and the Company completed target enrollment in the Phase 1 Part 2 monotherapy dose expansion study in the first quarter of 2026.

In December 2025, a dose cap was implemented for high body weight patients. Based on internal pharmacokinetic (PK) simulation modeling indicating that MICVO exposures with dose capping and adjusted ideal bodyweight (AIBW) dosing are expected to be comparable, dose capping was prioritized due to its operational simplicity and speed of implementation. The updated results reported today focus on patients treated at 5.4 mg/kg Q3W with a dose cap.

About Micvotabart Pelidotin (MICVO)

Micvotabart pelidotin (MICVO, formerly PYX-201) is an antibody-drug conjugate (ADC) that uniquely targets extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix. MICVO is designed to generate a multi-pronged attack on difficult-to-treat cancers by directly killing cancer cells, reducing extra-cellular matrix density, inhibiting tumor angiogenesis and mobilizing an anti-tumor immune response.

MICVO received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of adult patients with R/M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)-1 therapy.

About Pyxis Oncology, Inc.

Pyxis Oncology, Inc. is a clinical-stage biopharmaceutical company developing therapeutics for difficult-to-treat cancers. The Company's lead candidate, micvotabart pelidotin (MICVO), is a first-in-concept antibody-drug conjugate (ADC) that targets extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix (ECM). EDB+FN is selectively overexpressed in the tumor microenvironment of a wide range of solid tumors and largely absent from normal adult tissues. MICVO is designed to treat solid tumors through a three-pronged mechanism of action: direct cancer cell killing, bystander effect and immunogenic cell death. MICVO is currently being evaluated as monotherapy in a Phase 1 clinical study in patients with recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) and in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a Phase 1/2 clinical study in patients with R/M HNSCC and other solid tumors. Pyxis Oncology is focused on advancing MICVO, with the goal of improving outcomes for patients living with R/M HNSCC and contributing to meaningful progress in cancer treatment.

To learn more, visit www.pyxisoncology.com or follow us on [LinkedIn](#).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.



Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this press release, including without limitation statements regarding the Company's plans to develop, manufacture and commercialize its product candidate, including micvotabart pelidotin ('MICVO'); preliminary data, timing and progress of the Company's ongoing clinical trials; the expected results of the Company's clinical trials; the ability of preliminary, initial and topline clinical data to de-risk MICVO and be confirmed with clinical trial progression, including the safety, tolerability, and potential efficacy of MICVO; the potential differentiation, advantage or effectiveness of MICVO compared to other approved products or products in development; the dosage and treatment potential of MICVO; the size and future of the market; the plans and objectives of management, and the future results of operations and financial position of the Company, are forward-looking statements. These statements are neither promises nor guarantees, but are statements that involve known and unknown risks, uncertainties and other important factors that are in some cases beyond the Company's control that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the risks inherent in drug research and development, the Company's projected cash runway and potential needs for additional funding; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in or failure to obtain regulatory approvals; the Company's reliance on third parties and collaborators to conduct clinical trials, manufacture its product candidate, and develop and commercialize its product candidate; and the Company's ability to compete successfully against other drug candidate. Accordingly, investors should not rely upon forward-looking statements as predictions of future events. Except as required by applicable law, the Company undertakes no obligation to update publicly or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Additionally, investors should read risk factors in the section titled "Risk Factors" set forth in Part II, Item 1A. of the Company's Quarterly Report on Form 10-Q filed on August 13, 2026, and the Company's other filings, each of which is on file with the Securities and Exchange Commission.

Pyxis Oncology Contact

IR@pyxisoncology.com

Pyxis Oncology MICVO Clinical Update

September 9, 2026



Forward-Looking Statements

This presentation contains forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation, including without limitation statements regarding the Company's plans to develop, manufacture and commercialize its product candidate, including micvotabart pelidotin ('MICVO'); preliminary data, timing and progress of the Company's ongoing clinical trials; the expected results of the Company's clinical trials; the ability of preliminary, initial and topline clinical data to de-risk MICVO and be confirmed with clinical trial progression, including the safety, tolerability, and potential efficacy of MICVO; the potential differentiation, advantage or effectiveness of MICVO compared to other approved products or products in development; the dosage and treatment potential of MICVO; the size and future of the market; the plans and objectives of management, and the future results of operations and financial position of the Company, are forward-looking statements. These statements are neither promises nor guarantees, but are statements that involve known and unknown risks, uncertainties and other important factors that are in some cases beyond the Company's control that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the risks inherent in drug research and development, the Company's projected cash runway and potential needs for additional funding; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in or failure to obtain regulatory approvals; the Company's reliance on third parties and collaborators to conduct clinical trials, manufacture its product candidate, and develop and commercialize its product candidate; and the Company's ability to compete successfully against other drug candidates. Accordingly, investors should not rely upon forward-looking statements as predictions of future events. Except as required by applicable law, the Company undertakes no obligation to update publicly or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Additionally, investors should read risk factors in the section titled "Risk Factors" set forth in Part II, Item 1A. of the Company's Quarterly Report on Form 10-Q filed on August 13, 2026, and the Company's other filings, each of which is on file with the Securities and Exchange Commission.

Pyxis Oncology – Meet the Team



Tom Civik, MBA
Chief Executive Officer

FivePrime FOUNDATION MEDICINE Genentech



Marsha Crochiere, PhD
VP, Head of Translational Medicine & Research

Vigeo Karyopharm



Tom Dorney, MS, MBA
SVP, Strategy & Financial Planning

IMMUNOVANT janssen



Brian Freeman, MBA
Chief Program Officer

immun-gen FCGHORN THERAPEUTICS Genentech



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Alan L. Ho, MD, PhD, is Chief of the Head and Neck Oncology Service and an attending medical oncologist at Memorial Sloan Kettering Cancer Center. He specializes in the treatment of head and neck cancers, including thyroid, salivary gland, and head and neck squamous cell cancers. Dr. Ho is also a translational clinical researcher whose work focuses on developing innovative and personalized therapies for patients with head and neck malignancies.

MICVO is Uniquely Positioned to Become a Meaningful Treatment Option for Patients with Cancer

PROGRAM	FIRST-IN-CONCEPT ADC Novel ADC target in the tumor extracellular matrix
NEED	SIGNIFICANT UNMET NEED IN 2L+ HNSCC DRIVEN BY POTENTIAL CHANGE IN 1L Inadequate options for 2L+ HNSCC; 21K+ US patients by 2030, >\$4B US Total Addressable Market (TAM)
STUDY	EVALUATE MICVO IN 2L+ HNSCC AFTER CURRENT & POTENTIAL FUTURE 1L TREATMENTS Assess impact of prior therapy and HPV status
RESULTS	SUBSTANTIAL EFFICACY IMPROVEMENT WITH MANAGEABLE SAFETY Meaningful survival and response benefit and a safety profile consistent with approved ADCs
PATH FORWARD	PIVOTAL-READY, ROOM TO EXPAND Phase 3 initiation planned for mid-2027; potential to develop beyond 2L+ HNSCC

Micvotabart Pelidotin (MICVO)

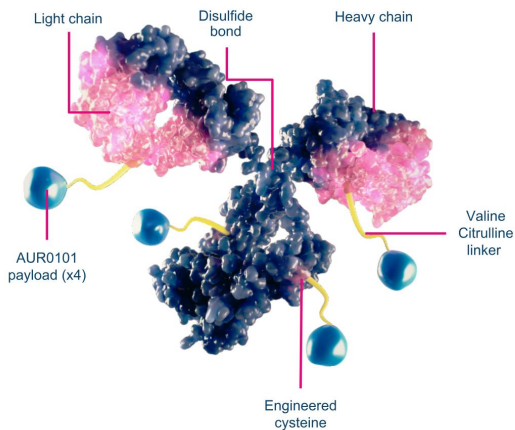
First-in-Concept ADC Designed to Target EDB+FN in the Tumor Extracellular Matrix



MICVO is the First ADC with a Target in the Tumor ECM, Not on the Cell Surface

Composed of a mAb targeting EDB+FN with site-specific protease-cleavable linkers and optimized auristatin payloads

MICVO Construct

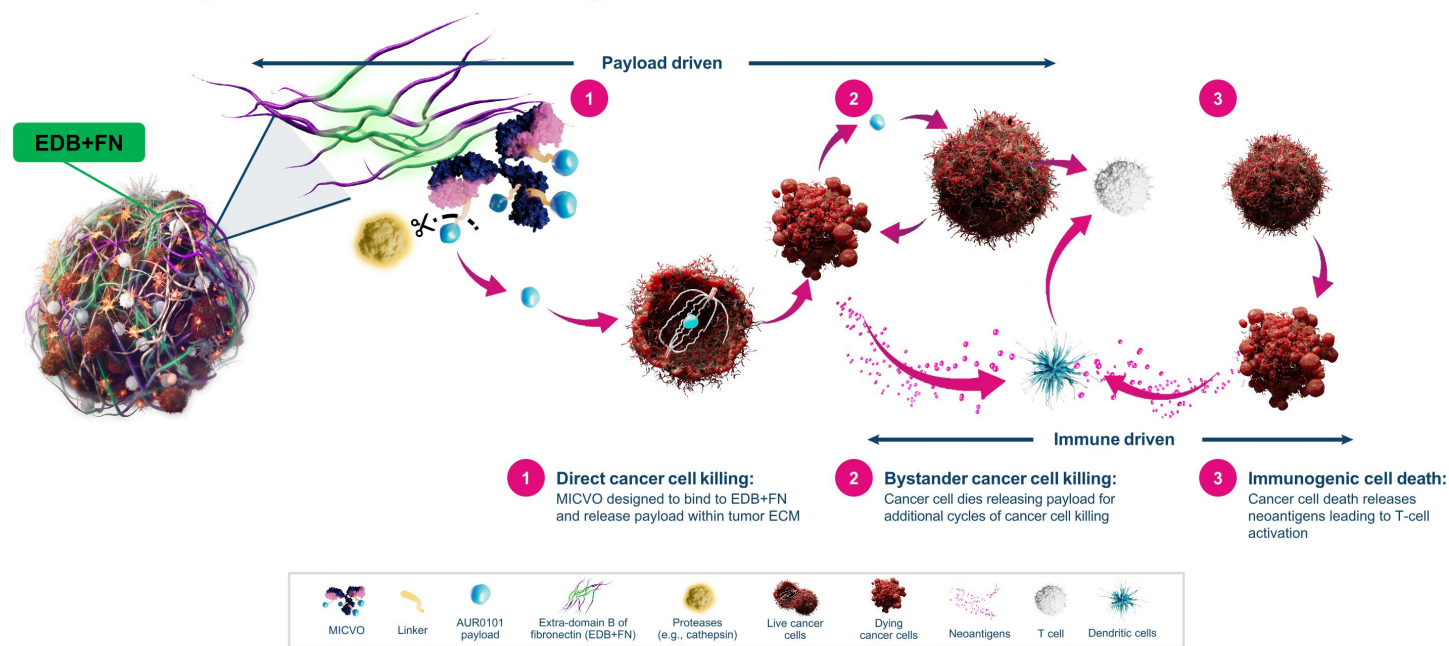


Key Potential Advantages

PURPOSE-BUILT	- Structural integrity with high avidity-driven binding Site-specific, extracellular cleavable valine citrulline linkers
PREDICTABLE	Uniform DAR of 4 potential provides improved therapeutic window Reduced free payload in serum, C_{max} ~4 days post administration
POTENT	- Four optimized auristatin 0101 microtubule directed payloads - Designed to maximize broad tumor-killing and biological potency
PERMEABLE	- Optimized membrane diffusion to enhance bystander killing Rapid payload clearance to potentially reduce off-target effects

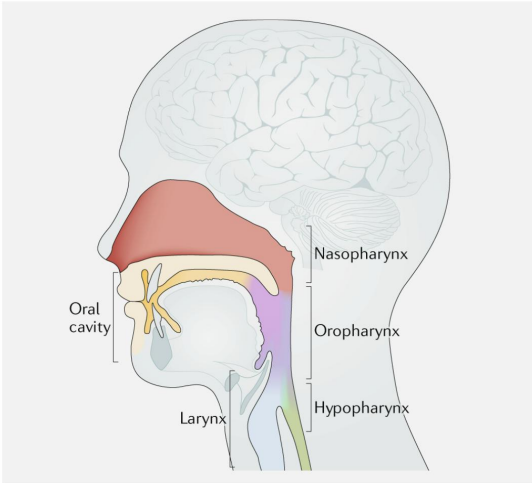
MICVO Designed to Deliver Potent Anti-Tumor Activity Through Three-Pronged MOA

MICVO is designed for extracellular linker cleavage in the TME which initiates the MOA



Rationale to Pursue HNSCC as the Initial Tumor Type to Investigate with MICVO

HNSCC



Key Supporting Data

TME FEATURES	• Robust expression of EDB+FN in HNSCC tumor stroma • Immune inflamed • Mature stroma containing straight, angular ECM fibers
IN VIVO EFFICACY DATA	• Anti-tumor activity in multiple HNSCC PDX models, with higher expression of enzyme and stromal gene signatures • Anti-tumor activity observed in an immune-refractory HNSCC syngeneic model • Promotes a favorable immune TME
CLINICAL SIGNAL	• Strong monotherapy signal in dose escalation confirmed in 2L+ expansion cohort • Efficacy observed regardless of HPV status or prior therapy • Encouraging activity in 1L combination with pembrolizumab

Similar TME features, in vivo efficacy data, and clinical signals observed in multiple solid tumors

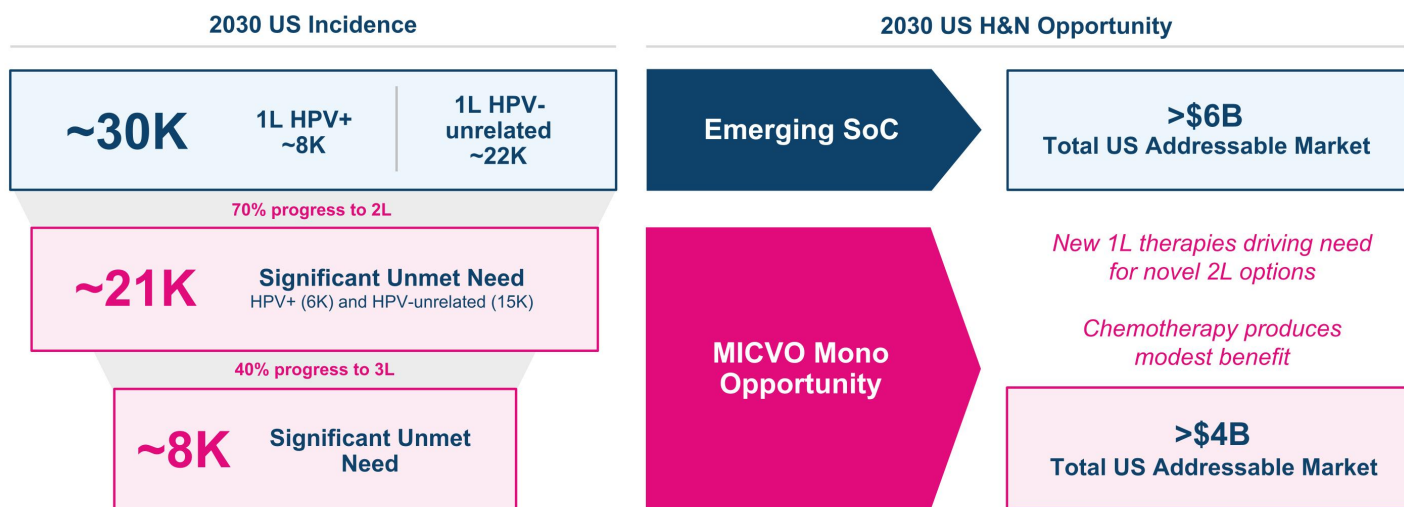
Unmet Need & Opportunity in 2L+ R/M HNSCC



By 2030, an Evolving 1L Landscape and Inadequate Treatment Options in 2L+ Create Significant Unmet Need

Next-gen EGFRi therapies emerging in 1L create significant demand for non-EGFRi mechanism in 2L+

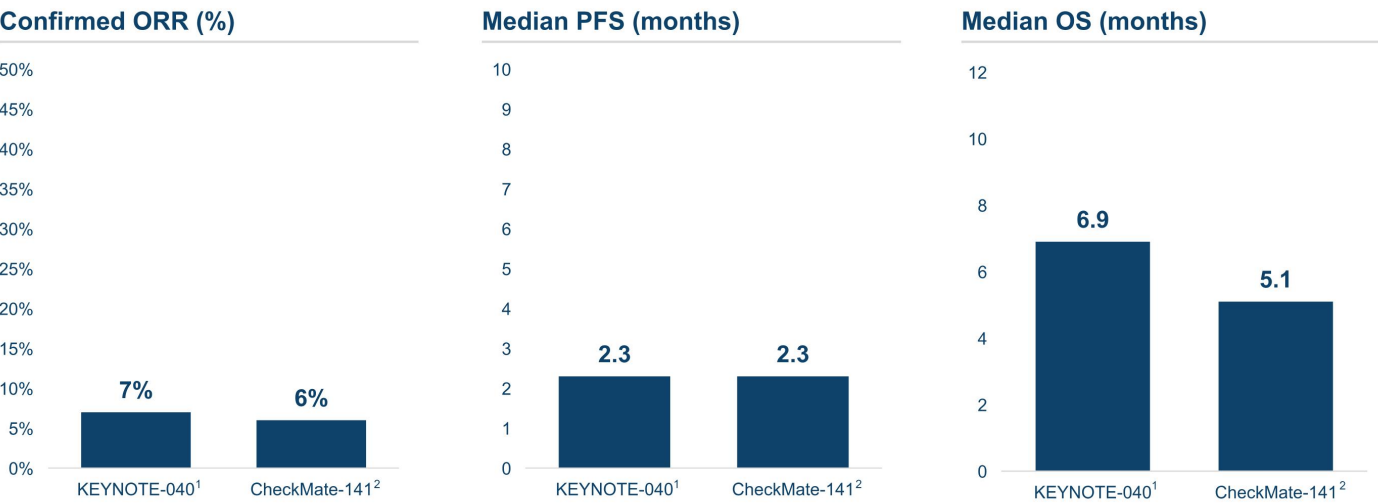
HNSCC: 7th Most Common Oncology Tumor Type¹



Limited Options Exist for Efficacious and Durable Therapies in 2L+ HNSCC

2L+ R/M HNSCC

Control arm data from 2L+ R/M HNSCC randomized trials show modest benefit



Unlocking the Potential of a First-in-Concept ADC

HNSCC Identified as Initial Tumor Type for Clinical Development



MICVO's Global Development Advanced from Dose Escalation to Expansion in R/M HNSCC with a Dose Cap

Expansion arm 1 and 2 designed to study MICVO after current and potential future 1L treatments

PART 1 [Dose Escalation]

Monotherapy ➔

**Dose
escalation
including
R/M HNSCC**

2024

NOV 2024

Mono Dose Escalation

- ✓ **Established dose range** of 3.6–5.4 mg/kg
- ✓ **Initiated expansion** at 5.4 mg/kg in R/M HNSCC

PART 2 [Dose Expansion]

ARM 1

2L+ R/M HNSCC dose expansion — post-platinum & anti-PD-(L)1

Target enrollment N~20

ARM 2

2L+ R/M HNSCC dose expansion — post-EGFRi & anti-PD-(L)1

Target enrollment N~20

2025

DEC 2025

Preliminary Mono Dose Expansion

- ✓ **Compelling efficacy** data in 2L+ R/M HNSCC (46% cORR) (HPV- and prior therapy- agnostic)
- ✓ **Implementation of dose cap** to mitigate toxicities observed in high body weight patients

2026

SEP 2026

Mono Dose Expansion with a Dose Cap

- ✓ **Dose cap unlocks MICVO's full potential** at 5.4 mg/kg
- ✓ **Compelling efficacy data with manageable safety**

Key Inclusion Criteria

- Histologically or cytologically confirmed HNSCC
- Primary tumor location is Oropharynx, Hypopharynx, Larynx, or Oral Cavity¹
- R/M disease progressed on/after platinum-based therapy and a PD-(L)1 inhibitor
- RECIST v1.1 measurable disease
- ECOG PS 0-1

All Patients to Dose Cap Subgroup



Efficacy Evaluable Definition
Patients who met all three of the following criteria:

1. Received ≥1 dose of MICVO
2. Had a baseline disease assessment
3. Had at least 1 post-baseline disease assessment evaluable per RECIST v1.1 and/or discontinued treatment due to death or disease progression

Dose Cap Patient Demographics and Disease Characteristics

2L+ R/M HNSCC

Evenly proportioned HPV population reflects poor performance, heavily pre-treated and emerging EGFRi-experienced

2L+ R/M HNSCC	Dose Cap (N=35)
Race, n (%)	
White	29 (82.9%)
Black or African American	2 (5.7%)
Asian	1 (2.9%)
Native Hawaiian or Other	1 (2.9%)
Not reported/Unknown	2 (5.7%)
Age (years)	
Median (min-max)	65 (41-74)
Baseline Weight (kg)	
Median (min-max)	66.8 (47.8-99.2)
Calculated BMI (kg/m2)	
Median (min-max)	22.4 (18.8-31.3)
Gender, n (%)	
Male	29 (82.9%)
Female	6 (17.1%)
Baseline ECOG Performance Status, n (%)	
0	12 (34.3%)
1	23 (65.7%)

2L+ R/M HNSCC	Dose Cap (N=35)
Primary Cancer Site, n (%)	
Oropharynx	22 (62.9%)
Oral cavity	6 (17.1%)
Larynx	7 (20.0%)
HPV Status (local)	
HPV+ Oropharyngeal SCC, n (%)	18 (51.4%)
HPV-Unrelated, n (%)	17 (48.6%)
Prior Systemic Therapy, Median Lines (min-max)	
3 (1-5)	
Prior Systemic Therapy in R/M Setting, Median Lines (min-max)	
2 (1-4)	
Taxane, n (%)	25 (71.4%)
Platinum, n (%)	35 (100.0%)
Anti-PD-(L)1 Agent, n (%)	35 (100.0%)
EGFRi, n (%)	20 (57.1%)
Cetuximab ¹	15
Petosemtamab ¹	3
Ficerafusp alpha ¹	2



Abbreviations: HPV: human papillomavirus; SCC: squamous cell carcinoma; EGFR: epidermal growth factor receptor; IO: immuno-oncology; ECOG: Eastern Cooperative Oncology Group; BMI: body mass index; PR: partial response; N/n: number of patients.
References: 1. cetuximab – Eli Lilly and Company & Merck KGaA, petosemtamab – Genmab A/S, ficerafusp alpha – Bicara Therapeutics

MICVO Monotherapy Showed Best-in-Disease Potential in 2L+ R/M HNSCC

5.4 mg/kg Q3W with Dose Cap



MICVO Achieved Substantial Survival Benefit Regardless of Prior Therapy or HPV Status

Rapid and deep responses achieved with a manageable safety profile



Rapid and Deep Responses

36% cORR | 94% DCR

75% of responders achieved response at the first scan

83% responders achieved >50% reduction in tumor size¹



Substantial Survival

6.2 months mPFS

79% 12-month OS probability

Benefit achieved across HPV status and prior-treatment subgroups



Manageable Safety

No new safety signals²

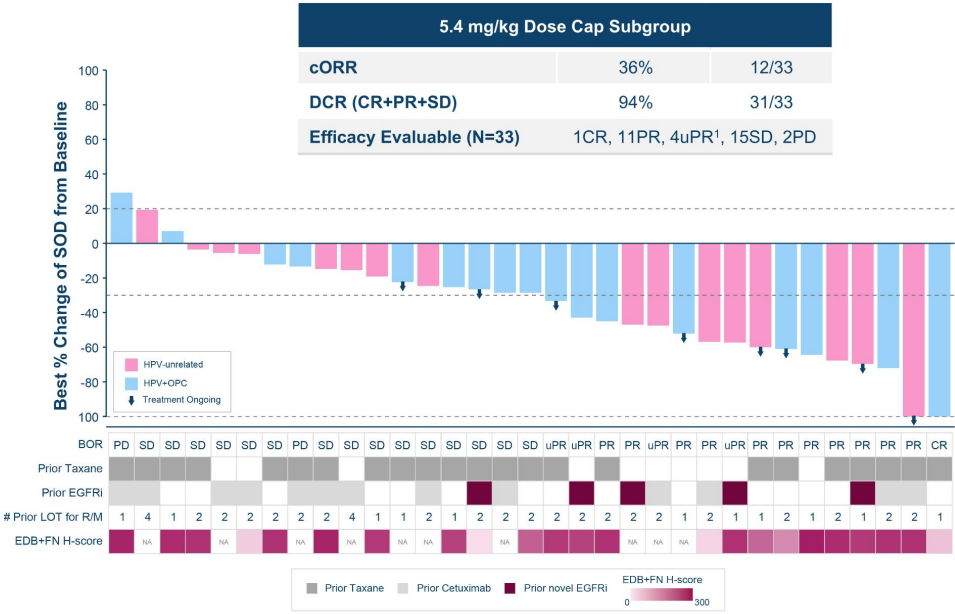
Tolerability profile expected & consistent with prolonged Auristatin exposure

Dose cap reduced the frequency and severity of safety events in high body weight patients

Emerging profile supports **rapid initiation of a pivotal trial**

MICVO Consistently Achieved Robust Response Rates Across Key Patient Subgroups

2L+ R/M HNSCC



HPV Status

35% cORR HPV+ OPC (N=17)	38% cORR HPV-Unrelated (N=16)
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Prior EGFRi

28% cORR Yes (N=18)	47% cORR No (N=15)
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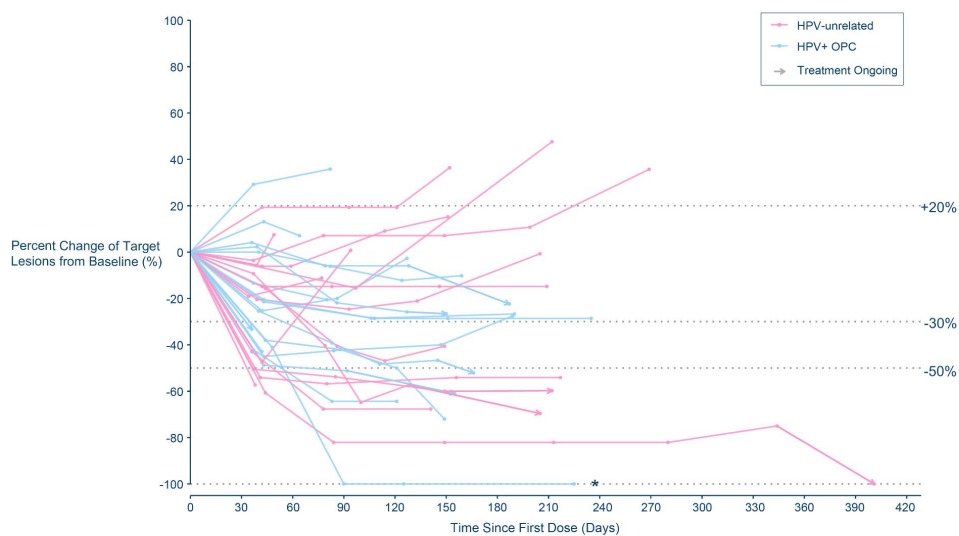
Among the 18 patients with prior EGFRi, the 5 with a prior novel EGFRi experienced **cORR of 40%**

Prior Taxane

35% cORR Yes (N=23)	40% cORR No (N=10)
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MICVO Achieved Rapid and Deep Responses

MICVO 5.4 mg/kg Q3W with Dose Cap



Key Takeaways

RAPID RESPONSES

75%

Responses occurred by first scan

DEEP RESPONSES

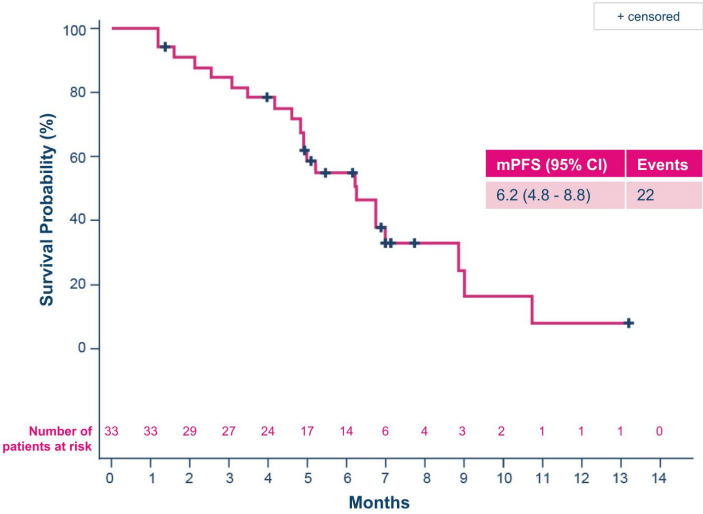
83%

Responders achieved greater than 50% tumor reduction¹

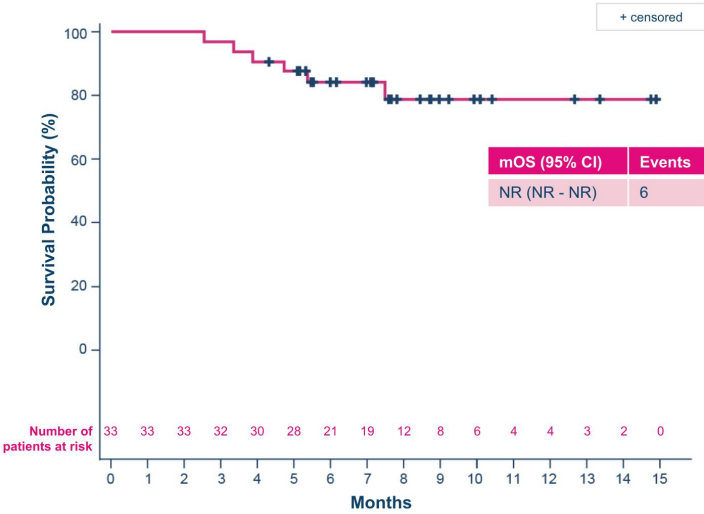
MICVO Demonstrated Substantial Survival Benefit

2L+ R/M HNSCC

MICVO 5.4 mg/kg Q3W with Dose Cap	
	Efficacy Evaluable (N=33)
mPFS months, (95% CI)	6.2 months (4.8 - 8.8)
6-month PFS probability %, (95% CI)	54.9% (35.8, 70.4)



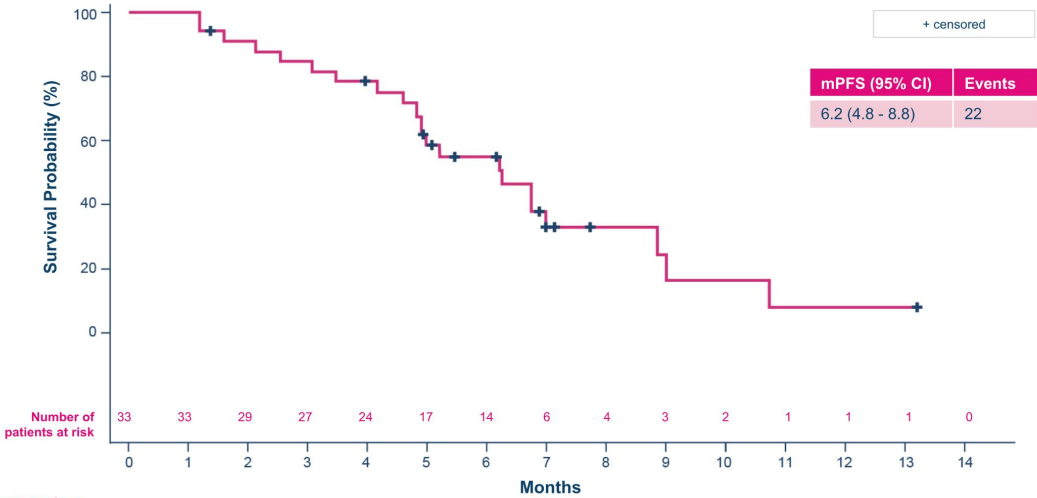
MICVO 5.4 mg/kg Q3W with Dose Cap	
	Efficacy Evaluable (N=33)
mOS months, (95% CI)	NR (NR - NR)
12-month OS probability %, (95% CI)	79.0% (58.1, 90.3)



MICVO Consistently Achieved High Survival Benefit Across Key Patient Subgroups

2L+ R/M HNSCC

MICVO 5.4 mg/kg Q3W with Dose Cap	
	Efficacy Evaluable (N=33)
mPFS months, (95% CI)	6.2 mos (4.8 – 8.8)
6-month PFS probability (95% CI), %	54.9% (35.8, 70.4)



PYXIS
ONCOLOGY

Abbreviations: HPV: human papillomavirus; OPC: oropharyngeal cancer; EGFRi: EGFR inhibitor; mPFS: median progression-free survival; PFS: progression-free survival; CI: confidence interval; Q3W: every 3 weeks; N: number of patients.

HPV Status	
mPFS: 6.2 HPV+ OPC (N=17)	mPFS: 5.9 HPV-Unrelated (N=16)

Prior EGFRi	
mPFS: 5.0 Yes (N=18)	mPFS: 8.8 No (N=15)
Among the 18 patients with prior EGFRi, the 5 with a prior novel EGFRi experienced mPFS of 5.8 months	

Prior Taxane	
mPFS: 6.2 Yes (N=23)	mPFS: 4.9 No (N=10)

TRAEs

	5.4 mg/kg with Dose Cap (N=35)
Treatment duration – median days (range)	120 (21-470)
All TRAEs	32 (91.4%)
TRAEs of CTCAE Grade ≥ 3	19 (54.3%)
Non-Hematologic TRAEs of CTCAE Grade ≥ 3	15 (42.9%)
Serious TRAEs	5 (14.3%)
TRAEs leading to treatment discontinuation ¹	5 (14.3%)
TRAEs leading to treatment discontinuation days, median (min-max)	162 (104-212)
TRAEs leading to dose reduction	14 (40.0%)
Treatment related deaths (Grade 5)	0

ADC Payload TRAEs of Interest

	5.4 mg/kg with Dose Cap (N=35)	
	Gr1/2	Gr3
Cutaneous	17 (48.6%)	2 (5.7%)
Peripheral Neuropathy	14 (40.0%)	6 (17.1%)
Peripheral Neuropathy days to onset, median (min-max)	82 (3-157)	166 (85-197)
Ocular	10 (28.6%)	2 (5.7%)
Pneumonitis	4 (11.4%)	0

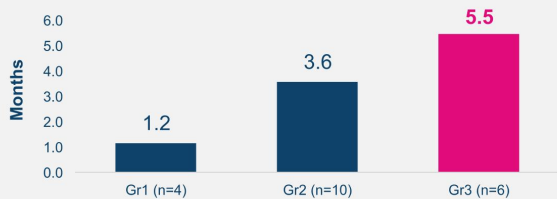


Abbreviations: ADC: antibody-drug conjugate; TRAE: treatment-related adverse event; CTCAE: Common Terminology Criteria for Adverse Events; Gr: grade; N: number of patients.
Notes: 1. TRAEs leading to discontinuation, N=1 Ocular, N=1 Muscle Weakness, N=3 Peripheral Neuropathy

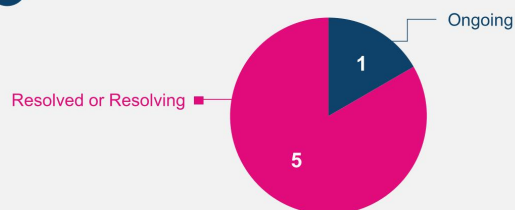
Late-Onset, Often Reversible Peripheral Neuropathy Observed in Patients who Experienced Meaningful Clinical Benefit on MICVO

Clinical benefit preceded onset of neuropathy, providing an opportunity for early detection and timely dose modification to preserve therapeutic benefit

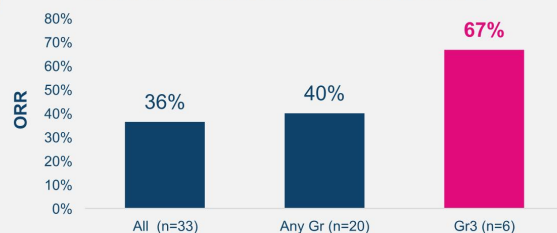
1 Time to Gr3 PN Onset is 5+ Months



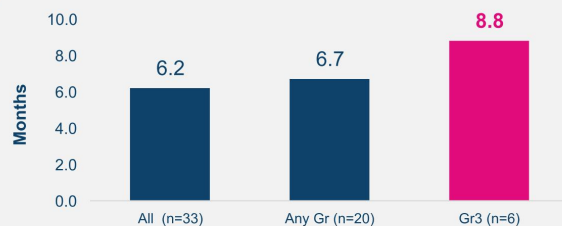
2 Majority of Gr3 PN Resolved or Resolving



3 Gr3 PN Patients Showed 67% cORR



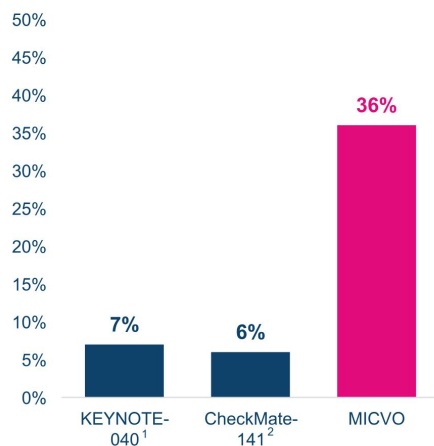
4 Gr3 PN Patients Showed 8.8 Months mPFS



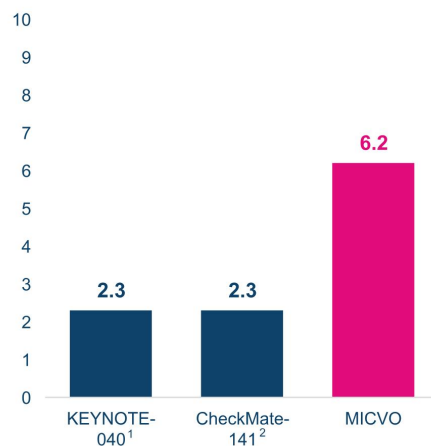
MICVO Response and Survival Benefit Exceeded Benchmarks

MICVO data represented >5X improvement in ORR, >2X improvement on mPFS and significant improvement on mOS compared to historical control arm data in 2L+ R/M HNSCC

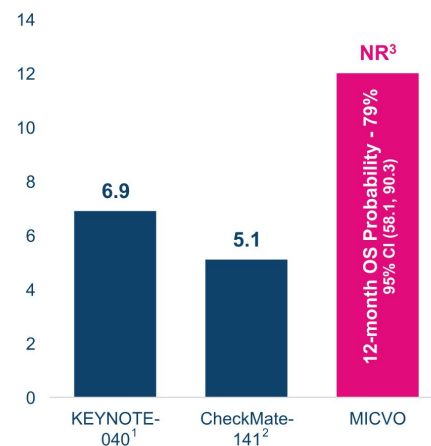
Confirmed ORR (%)



Median PFS (months)



Median OS (months)



Abbreviations: ORR: objective response rate; mPFS: median progression-free survival; PFS: progression-free survival; mOS: median overall survival; OS: overall survival; NR: not reached; N: number of patients.

Note: This analysis is the aggregation of results across independent studies. Cross-trial comparison only; no head-to-head trial of MICVO versus these agents has been conducted. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2.

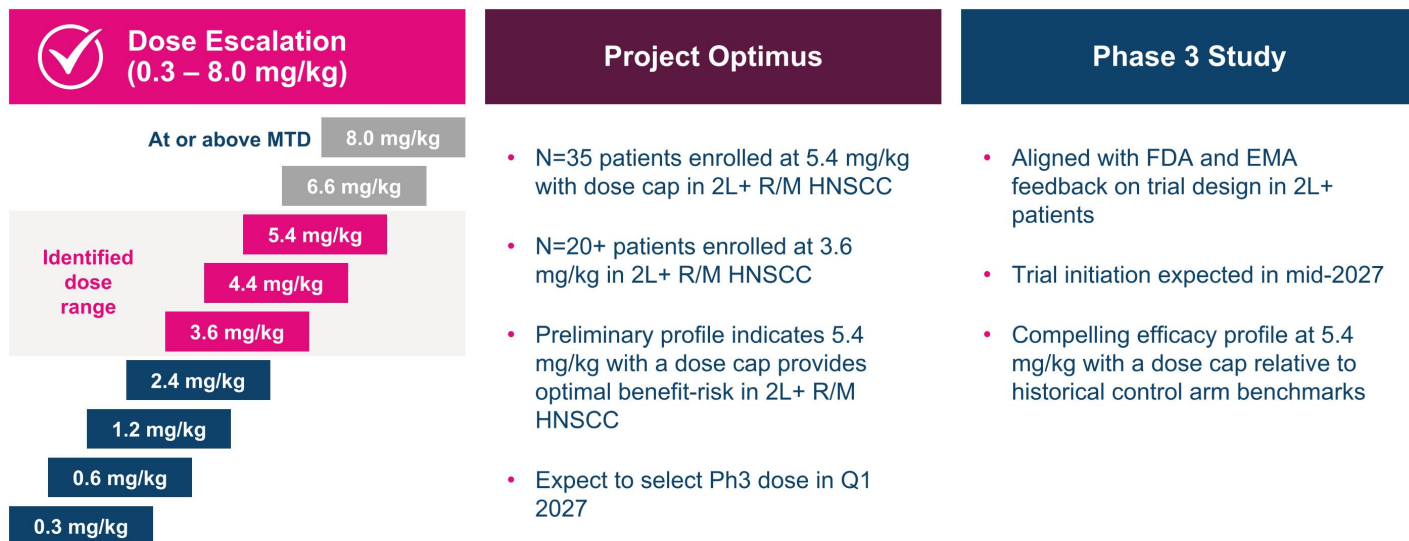
References: 1. KEYNOTE-040: Control arm (N=248) included Cetuximab/Methotrexate/Docetaxel; Pembrolizumab arm observed cORR=11%; mPFS=2.1 months; mOS=8.4 months (N=247); 2. CheckMate-141: Control arm (N=121) included Cetuximab/Methotrexate/Docetaxel; Nivolumab arm observed cORR=13%; mPFS=2 months; mOS=7.7 months (N=240); 3. Lower bound of 95% confidence interval for OS at 12 months is 58%

Next Steps in Clinical Development



Progressing with 5.4 mg/kg Versus 3.6 mg/kg to Satisfy Project Optimus

5.4 mg/kg with dose cap shows strong benefit-risk



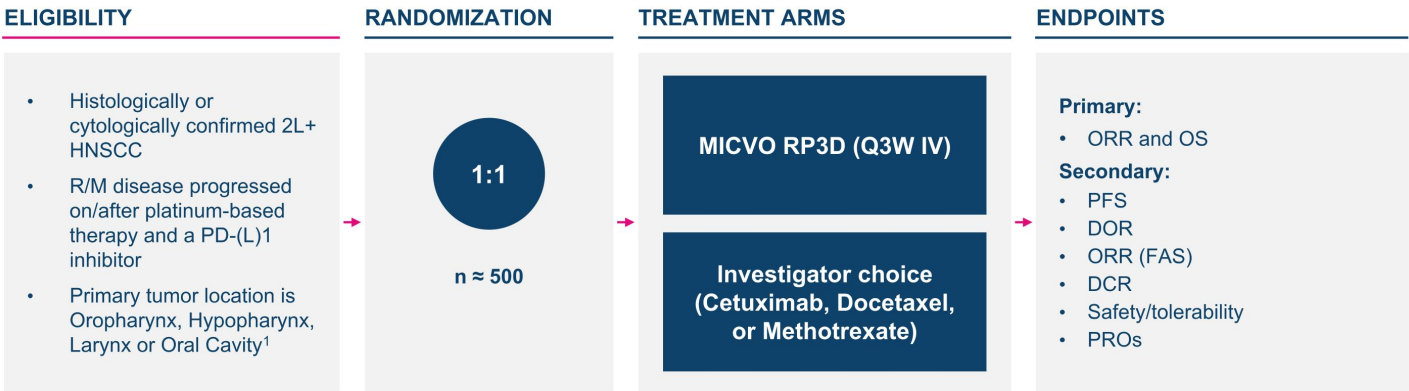
Aligned with FDA and EMA Feedback on Phase 3 Study Design

2L+ R/M HNSCC

Phase 3 initiation planned for mid-2027



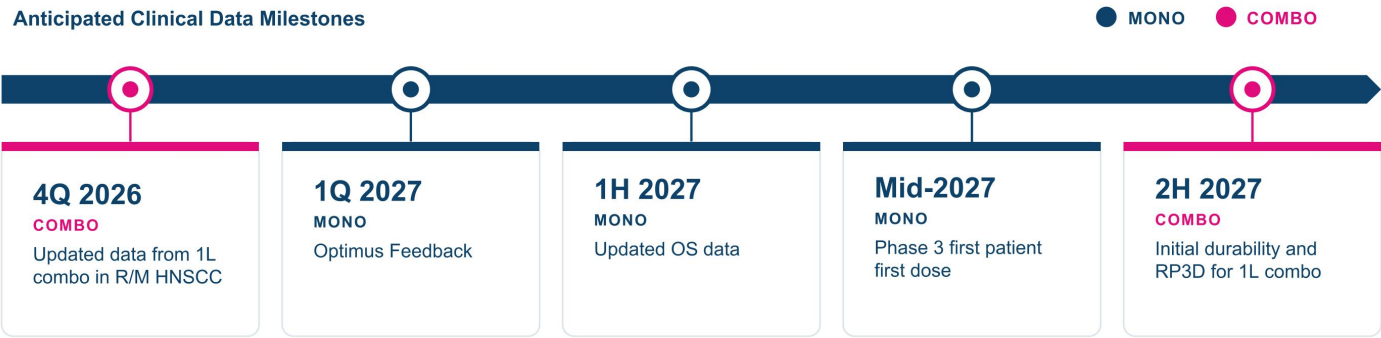
Randomized, open-label, 2-arm study
MICVO vs. investigator choice in 2L+ HNSCC



MICVO Key Value Drivers and Anticipated Clinical Data Timeline

Monotherapy and combination highlights, plus five milestones expected from 4Q 2026 through 2H 2027

2L+ R/M HNSCC MONO: MICVO 5.4 MG/KG WITH DOSE CAP - Novel MOA required as 1L treatment options change - Rapid and deep responses - Substantial survival benefit for entire 2L+ population - Manageable and well-understood safety profile - Clear path forward to pivotal start-up	1L HNSCC COMBO: MICVO + KEYTRUDA® (pembrolizumab) - Early signs of robust clinical activity in R/M HNSCC - Preclinical data support synergistic benefit with PD-1 blockade - Strong global enrollment - Differentiated MOA with potential to enhance checkpoint inhibition - Favorable preliminary safety and tolerability
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Charting a Course to Therapeutics for Difficult-to- Treat Cancers

September 9, 2026



MICVO Demonstrated Substantial Results for Entire 2L+ Population vs. Current and Emerging Therapies

					No EGFRi re-treatment expected in 2L
Population	Endpoint	MICVO (Pyxis Oncology)	KEYNOTE-040 ¹ and CheckMate-141 ¹ (Cetuximab, Docetaxel or Methotrexate)	CRB-701 ² (Corbus)	Petosemtamab ³ (Genmab)
All Comers	N	33	121-248	37	75
	cORR	36%	6%-7%	24%	36%
	mPFS (95% CI), months	6.2 (4.8-8.8)	2.3	4.2 (2.8-5.6)	4.9 (3.2-5.4)
	12-month OS probability (95% CI), %	79% (58.1, 90.3)	17-27%	Not disclosed	11.4 mo mOS



Abbreviations: OPSCC: Oropharyngeal Squamous Cell Carcinoma; IRR: Infusion Related Reactions
* NOTE: Note: This analysis is the aggregation of results across independent studies. Cross-trial comparison only; no head-to-head trial of MICVO versus these agents has been conducted. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2
1. Providing ranges from KEYNOTE-040 and CheckMate-141 studies; 2. Corbus pre-ASCO 2026 Presentation; 3. Merus ESMO Singapore 2024 Presentation

Solid Tumor ADC Dosing Approach Summary

Solid Tumor ADC	Dose Cap / AIBW	Highest % Gr3 AE observed at TBW	Target	Payload	Dose (mg/kg)	DAR	Approval Yr	2024 FY Sales
Kadcyla®	TBW	thrombocytopenia	HER2	DM1	3.6; Q3W	4	2013	\$2.3B
Enhertu®	TBW	Pneumonitis / ILD	HER2	TOPO1	5.4; Q3W	8	2019	\$4.2B
Padcev®	DC - 100kg	Neuropathy and Rash	Nectin-4	MMAE	1.25; D1,8,15 Q4W	4	2019	\$1.9B
Trodelyv®	TBW	Neutropenia	TROP2	SN38	10; D1D8 Q3W	8	2020	\$1.3B
Tivdak®	DC - 100kg	Neuropathy	Tissue Factor	MMAE	2; Q3W	4	2024	\$131M
Elahere®	AIBW	Intestinal obstruction & thrombocytopenia	Folate Receptor α	DM4	6; Q3W	3	2024	\$479M
Datroway®	DC - 90kg	Pneumonitis / ILD	TROP2	TOPO1	6; Q3W	4	2025	N/A
Emrelis™	DC - 100kg	Pneumonitis / ILD & Neuropathy	C-MET	MMAE	1.9; Q2W	4	2025	N/A

Not Approved / In Development

MICVO	DC & AIBW	Neuropathy	EDB+FN	AUR0101	5.4; Q3W	4
Varsetatug masetecan (Cytomx)	AIBW	Diarrhea	EpCAM	TOPO1	8.6 and 10; Q3W	8
IM-1021 (Immunome)	AIBW	TBD	ROR-1	TOP1	TBD	8
Sigvotatug vedotin (Pfizer)	AIBW	Pneumonitis / ILD	IB6	MMAE	1.8; Q2W	4