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)

September 9, 2026

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

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%)		
Not reported/Unknown	2 (5.7%)	**HPV Status (local)**	
Age (years)		HPV+ Oropharyngeal SCC, n (%)	18 (51.4%)
Median (min-max)	65 (41-74)	HPV-Unrelated, n (%)	17 (48.6%)
Baseline weight (kg)		**Prior Systemic Therapy, Median Lines (min-max)**	**3 (1-5)**
Median (min-max)	66.8 (47.8-99.2)	**Prior Systemic Therapy in R/M Setting, Median Lines (min-max)**	**2 (1-4)**
Calculated BMI (kg/m2)		Taxane, n (%)	25 (71.4%)
Median (min-max)	22.4 (18.8-31.3)	Platinum, n (%)	35 (100.0%)
Gender, n (%)		Anti-PD-(L)1 Agent, n (%)	35 (100.0%)
Male	29 (82.9%)	EGFRi, n (%)	20 (57.1%)
Female	6 (17.1%)	Cetuximab[1]	15
Baseline ECOG Performance Status, n (%)		Petosemtamab[1]	3
0	12 (34.3%)	Ficerafusp alpha[1]	2
1	23 (65.7%)		

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

BOSTON, Sept. 09, 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

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)
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	5.4 mg/kg 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

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 (3-151)	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.

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.

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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.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/f0e9ef4e-0fec-44af-b949-8e3588e22e42