Pyxis Oncology Announces Positive Preliminary Phase 1 Data for Micvotabart Pelidotin (MICVO) in Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

December 18, 2025

- *46% confirmed objective response rate (ORR) and 92% disease control rate (DCR) observed with MICVO as monotherapy in 2L+ R/M HNSCC at 5.4 mg/kg*

- *71% confirmed ORR and 100% DCR observed with MICVO in combination with KEYTRUDA® (pembrolizumab) in 1L/2L+ R/M HNSCC at 3.6 mg/kg and 4.4 mg/kg*

- *Updated data from ongoing Phase 1 monotherapy study in 2L+ R/M HNSCC expected mid-2026; updated data from ongoing Phase 1/2 study evaluating MICVO in combination with KEYTRUDA®, including in 1L/2L+ R/M HNSCC and other tumor types, expected 2H26*

- *Company to host webcast and conference call today at 8:30 a.m. ET*

BOSTON, Dec. 18, 2025 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today announced positive preliminary data from its ongoing Phase 1 clinical studies evaluating micvotabart pelidotin (MICVO), 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 (ECM), in patients with recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC). The update includes preliminary data from both the Phase 1 monotherapy study in 2L+ R/M HNSCC and the Phase 1/2 study evaluating MICVO in combination with Merck's (known as MSD outside of the US and Canada) anti-PD-1 therapy, pembrolizumab, in 1L/2L+ R/M HNSCC.

"The preliminary data for MICVO as monotherapy and in combination with pembrolizumab add to the growing body of evidence supporting MICVO's therapeutic potential and highlight its agility as a novel potential treatment option across the recurrent/metastatic head and neck squamous cell carcinoma landscape," said Lara S. Sullivan, M.D., President, Chief Executive Officer and Chief Medical Officer of Pyxis Oncology. "The emerging response rates and disease control observed across these studies are highly encouraging, and the lack of early disease progression supports confidence in the durability profile as we advance MICVO in clinical development. We look forward to sharing mature data from the ongoing trials next year."

"The current paradigm for treatment of recurrent/metastatic head and neck squamous cell carcinoma offers limited options and therapeutic mechanisms for our patients, so we are particularly pleased to observe a novel mechanism providing emerging evidence of such compelling benefit-risk profile," said Glenn J. Hanna, M.D., Director, Center for Cancer Therapeutic Innovation and Center for Salivary and Rare Head and Neck Cancers at Dana-Farber Cancer Institute, and Associate Professor of Medicine, Harvard Medical School. "As we look ahead to where the treatment landscape may include next-generation EGFR combination therapies as first-line options for select patients, many will still lack effective treatments, particularly in later lines – which remains a significant unmet clinical need. MICVO monotherapy presents an intriguing potential option for these later-line patients, while the initial data in combination with pembrolizumab also shows promising potential synergies in first-line patients."

The cutoff for all data reported below is as of November 3, 2025. Key findings are as follows:

Monotherapy
The ongoing MICVO Phase 1 monotherapy study is a two-part study. Part 1 was a dose escalation study across multiple doses and tumor types, with initial data shared in November 2024. Part 2, a dose expansion cohort at 5.4 mg/kg in 2L+ R/M HNSCC, is currently ongoing. The data below incorporate all R/M HNSCC patients dosed at 5.4 mg/kg in the MICVO Phase 1 monotherapy study.

- 18 patients were treated at 5.4 mg/kg; intravenous (IV) dosed every three weeks (Q3W)
  - 13 patients were evaluable for response (≥1 post-baseline scan within protocol limits, or discontinued early due to disease progression)
  - All patients treated had prior systemic therapy, including:
    - Median of 3 prior lines of therapy
    - 100% (18/18) had prior platinum-based therapy
    - 100% (18/18) had prior checkpoint inhibitor therapy
    - 67% (12/18) had prior taxane therapy
    - 50% (9/18) had prior EGFR targeting therapy
- Confirmed overall response rate (ORR) of 46% (6/13)[1], including 1 complete response by RECIST v1.1 (Response Evaluation Criteria in Solid Tumors v1.1).
  - Confirmed responses observed in both arms of dose expansion: post platinum & anti-PD(L)-1 experienced patients

(Arm 1) and post EGFRi and/or anti-PD(L)-1 experienced patients (Arm 2)
    - Arm 1: 60% confirmed ORR (N=5)
    - Arm 2: 25% confirmed ORR (N=4)
  - Confirmed responses observed in patients with HPV-positive, HPV-negative, and HPV-not applicable tumors
- Disease control rate (DCR) of 92% (12/13)
  - 12 patients demonstrated significant tumor regression or tumor control
  - 1 patient with progressive disease had a verrucous subtype of HNSCC, which is often resistant to chemotherapy and typically managed surgically
- MICVO was generally well tolerated, with no Grade 4 ADC payload treatment-related adverse events (TRAEs) of interest observed. No Grade 5 events occurred.
  - TRAEs were observed in 89% (16/18) of patients
  - Grade ≥3 TRAEs occurred in 56% (10/18) of patients
  - TRAEs leading to treatment discontinuation were observed in 28% (5/18) of patients
    - 100% (5/5) of patients who had TRAEs leading to treatment discontinuation had “high bodyweight” (defined as at least 10% above adjusted-ideal bodyweight)
    - Adjusted Ideal Bodyweight (AIBW) dosing, which has demonstrated improved tolerability without sacrificing activity in clinical studies of other ADCs, is planned to be implemented in ongoing and future clinical studies

Combination Therapy

The ongoing MICVO Phase 1/2 study evaluating MICVO in combination with KEYTRUDA® is part of a Clinical Trial Collaboration Agreement with Merck (known as MSD outside the US and Canada) and is currently in dose escalation across multiple doses and tumor types, including 1L/2L+ R/M HNSCC. The data below incorporate all R/M HNSCC patients dosed in the MICVO Phase 1/2 combination study at 3.6 mg/kg and 4.4 mg/kg.

- 7 patients were treated in total, 4 at 3.6 mg/kg and 3 at 4.4 mg/kg of MICVO, plus fixed dose 200 mg of pembrolizumab; IV Q3W
  - All patients were evaluable for response (≥1 post-baseline scan within protocol limits, or discontinued early due to disease progression)
  - All patients treated to date were HPV-positive
    - Enrollment of HPV-negative and HPV-not applicable patients is anticipated as additional global clinical trial sites are activated
  - All patients treated had prior systemic therapy, including:
    - N=4, 1L HNSCC, median of 1 prior therapy
      - 100% (4/4) had prior platinum-based therapy administered with radiation in the adjuvant or definitive setting
      - 25% (1/4) had prior taxane administered in the neoadjuvant setting
    - N=3, 2L+ HNSCC, median of 3 prior lines of therapy
      - 100% (3/3) had prior platinum-based therapy
      - 100% (3/3) had prior checkpoint inhibitor therapy
      - 33% (1/3) had prior taxane therapy
- Confirmed overall response rate (ORR) of 71% (5/7)[1]
  - Responses occurred across a range of PD(L)-1 CPS scores (CPS ≥1 to CPS >20)
  - Responses were observed in patients who received and had disease progression following prior checkpoint inhibitor treatment
- DCR of 100% (7/7)
  - All 7 patients demonstrated significant tumor regression
- MICVO was generally well tolerated, with no Grade 3 or Grade 4 ADC payload TRAEs of interest observed. No Grade 5 events occurred.
  - TRAEs were observed in 86% (6/7) of patients
  - There were no TRAEs leading to treatment discontinuation
  - Lack of overlapping toxicities between MICVO and KEYTRUDA® observed to date

MICVO Next Steps

In mid-2026, Pyxis Oncology plans to present updated data from the ongoing Phase 1 monotherapy study in 2L+ R/M HNSCC, which is expected to include additional patients and initial durability data. In the second half of 2026, the company also plans to present updated data from the ongoing Phase 1/2 study evaluating MICVO in combination with pembrolizumab, including in 1L/2L+ R/M HNSCC and other tumor types.

Pyxis Oncology has received FDA alignment on the clinical trial design for a planned pivotal monotherapy study in 2L + R/M HNSCC. The Company is currently evaluating the path forward to pivotal studies for MICVO as monotherapy and in combination with pembrolizumab, respectively, and expects to provide additional detail in 2026.

Company Update

Pyxis Oncology completed sale of its rights to royalties from the commercialization of Enzeshu® (Suvemcitug for Injection) for a one-time cash

payment of $11 million. This non-dilutive funding will support the development of MICVO. As part of Pyxis Oncology's acquisition of Apexigen, Inc. in August 2023, the Company acquired rights to royalties on Enzeshu and another asset discovered using APXiMAB, Apexigen's proprietary antibody discovery platform. The Company's current cash runway is expected to fund operations through data milestones and into the fourth quarter of 2026.

Conference Call Information
Pyxis Oncology will host a live conference call and webcast at 8:30 a.m. ET today to review the preliminary Phase 1 clinical trial data. Participants may register for the conference call here. A webcast of the call will also be available under "Events and Presentations" in the Investors section of the Pyxis Oncology website at https://ir.pyxisoncology.com/. The archived webcast will be available on Pyxis Oncology's website approximately two hours after the conference call and will be available for 30 days following the call.

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 tumor cell killing, bystander effect and immunogenic cell death. MICVO is currently being evaluated in Phase 1 clinical studies in patients with recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) and other solid tumors, both as monotherapy and in combination with Merck's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab). 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 and follow us on LinkedIn.

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.

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

Dr. Hanna receives institutional research support and funding from, and has served in a consulting or advisory role for, Pyxis Oncology.

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 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 their product candidates, and develop and commercialize their 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 November 3, 2025, and our other filings, each of which is on file with the Securities and Exchange Commission.

Pyxis Oncology Contact
Alex Kane
IR@pyxisoncology.com

Media
Cailyn McCutcheon
Real Chemistry
cmccutcheon@realchemistry.com

_____

[1] One patient for monotherapy and one patient for combination therapy confirmed response after November 3, 2025 data cutoff