Pyxis Oncology to Present New Preclinical Data Supporting Development of First-In-Concept ADC Targeting EDB+FN in Tumor Microenvironment at AACR 2025

March 25, 2025

Expression data from patient-derived xenograft (PDX) mouse models exposed to micvotabart pelidotin (MICVO) indicate gene signatures associated with efficacy, deepening understanding of MOA and potential patient response

Combination of a mouse analog of MICVO and a mouse anti-PD-1 therapy in a syngeneic model resulted in significantly greater tumor regression than either treatment alone

Company advances MICVO into monotherapy and combination clinical trials with Merck's anti-PD-1 therapy, Keytruda ® (pembrolizumab), targeting recurrent and metastatic head and neck squamous cell carcinoma; preliminary data expected in 2H2025 and 1H2026

BOSTON, March 25, 2025 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, announced today that the Company will present new, positive preclinical data highlighting the potential of micvotabart pelidotin (MICVO, formerly referred to as PYX-201), a first-in-concept antibody-drug conjugate (ADC) that targets EDB+FN, a non-cellular structural component of the tumor extra-cellular matrix. These data will be presented in two poster sessions at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois, held from April 25 to 30, 2025.

"We are thrilled to present new preclinical data at AACR25 that further elucidate the innovative mechanism of action of MICVO, our first-in-concept EDB+FN targeting ADC, which leverages a unique non-cellular mechanism to drive anti-tumor activity," said Lara S. Sullivan, M.D., President, Chief Executive Officer and Chief Medical Officer of Pyxis Oncology. "As we advance MICVO both as a monotherapy and in combination with anti-PD-1 therapy in the clinic, we remain confident in our multi-pronged development strategy in recurrent and metastatic head and neck squamous cell carcinoma where we believe altering the extra-cellular matrix may effectively address a main cause of resistance to other therapies."

In a previous Phase 1 dose escalation study, it was established that MICVO has profound monotherapy effect on multiple tumor types with significant tumor regression. The Company has initiated the Part 2 monotherapy expansion cohorts of the ongoing Phase 1 clinical trial to evaluate MICVO in 2L and 3L recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) patients who have received prior platinum and PD-1 inhibitor therapy, and 2L and 3L R/M HNSCC patients who have received prior EGFRi and PD-1 inhibitor therapy.

Preliminary data from patients who have received prior platinum and PD-1 inhibitor therapy are expected in the second half of 2025 and preliminary data from patients who have received prior EGFRi and PD-1 inhibitor therapy are expected in the first half of 2026. Additionally, the Company initiated a Phase 1/2 combination study of MICVO and Merck's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab), in patients with R/M HNSCC and other advanced solid tumors, with the goal of identifying the recommended Phase 2 dose by mid-year 2025 and a readout of preliminary data in the second half of 2025.

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.

Presentation details at AACR are listed below, with all times in Central Time (CT):

- **Title:** Evaluation of PYX-201, an EDB+FN-targeting ADC, in a comprehensive PDX mini-trial study enables identification of gene signatures associated with anti-tumor activity
  Session Category: Experimental and Molecular Therapeutics
  Session Title: Therapeutic Approaches to Attack the Tumor Microenvironment
  Session Date and Time: Monday, April 28, 2025, 2:00 PM – 5:00 PM
  Location: Poster Section 24
  Poster Board Number: 5
  Published Abstract Number: 3120

- **Title:** The combination of anti-PD1 and a mouse analog of PYX-201, an antibody-drug conjugate targeting the extra-domain B splice variant of fibronectin (EDB+FN), shows greater anti-tumor efficacy than either treatment alone
  Session Category: Experimental and Molecular Therapeutics
  Session Title: Therapeutic Approaches to Attack the Tumor Microenvironment
  Session Date and Time: Monday, April 28, 2025, 2:00 PM – 5:00 PM
  Location: Poster Section 24
  Poster Board Number: 4
  Published Abstract Number: 3137

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

About Pyxis Oncology, Inc.
Pyxis Oncology, Inc. is a clinical stage company focused on defeating difficult-to-treat cancers. The company is efficiently building next generation therapeutics that hold the potential for monotherapy and combination indications. The lead product candidate, micvotabart pelidotin ("MICVO" formerly PYX-201), is an antibody-drug conjugate (ADC) that uniquely targets Extradomain-B Fibronectin (EDB+FN), a non-cellular structural component of the tumor extra-cellular matrix. MICVO has been evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors with a go-forward development focus on treating patients with recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) based on the strength of the HNSCC signal that emerged. 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.

To learn more, visit www.pyxisoncology.com or follow us on Twitter and LinkedIn.

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. These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of the Company's Annual Report on Form 10-K filed with SEC on March 18, 2025, and our other filings, each of which is on file with the Securities and Exchange Commission. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date hereof and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Pyxis Oncology Contact
Pamela Connealy
CFO and COO
ir@pyxisoncology.com