Pyxis Oncology Announces Portfolio Prioritization, Focusing Resources on its Lead Clinical Program, PYX-201

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- The Company will focus resources on advancing its lead asset, PYX-201

- PYX-201 is a novel first-in-concept antibody-drug conjugate (ADC) where significant RECIST responses were seen in head and neck squamous cell carcinoma (HNSCC) with additional potential in other solid tumors

- Current cash runway expected to fund development into 2H 2026

BOSTON, Dec. 19, 2024 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today announced a portfolio prioritization, focusing resources on advancing its lead clinical program, PYX-201, a first-in-concept antibody-drug conjugate (ADC) with a microtubule inhibitor (optimized auristatin) payload that uniquely targets Extradomain-B Fibronectin (EDB+FN), a non-cellular structural component within the tumor extracellular matrix.

In November 2024, Pyxis Oncology reported positive preliminary data from the ongoing Phase 1 dose-escalation study of PYX-201, evaluating its safety and efficacy in multiple solid tumor types. Among patients with HNSCC, PYX-201 achieved a confirmed 50% objective response rate (ORR) based on RECIST 1.1 criteria, including one complete response and a disease control rate (DCR) of 100% in six heavily pretreated HPV-positive and HPV-negative evaluable patients with a median of four prior lines of therapy.

Across six solid tumor types of interest at therapeutically active dose levels, including HNSCC, ovarian, non-small cell lung cancer (NSCLC), HR+/HER2- breast cancer, triple-negative breast cancer (TNBC), and sarcoma, PYX-201 (n=31) achieved a 26% ORR in the Phase 1 trial, with dose-dependent responses observed including patients who had previously progressed on taxanes. The data supports further development in both monotherapy and combination therapy expansion trials, including a frontline HNSCC study in combination with pembrolizumab, with patient dosing in both the monotherapy and combination therapy trials expected to begin in early 2025.

The portfolio prioritization further supports a robust development plan for PYX-201 in several dose expansion studies, including monotherapy in 2/3L HNSCC, in combination with pembrolizumab in 1/2L+ HNSCC, as well as pembrolizumab combination studies in other solid tumors including HR+/HER2- and triple-negative breast cancer. Preliminary data from these cohorts is expected across both the second half of 2025 and the first half of 2026.

Details on the PYX-201 Phase 1 dose-escalation trial and preliminary data presented in November are available on the Events & Presentations page in the Investor Relations section of Pyxis Oncology's website at ir.pyxisoncology.com.

Pipeline Prioritization
Pyxis Oncology's second clinical program, PYX-106 — a fully human IgG1 monoclonal antibody targeting Siglec-15 — is being deprioritized to allocate resources toward advancing the lead asset, PYX-201. As a result, Pyxis Oncology has decided to suspend further clinical investment in PYX-106, which was in-licensed from Biosion Inc., with Biosion retaining rights for Greater China.

To date, the Phase 1 monotherapy trial of PYX-106 enrolled 45 patients with advanced solid tumors. PYX-106 was observed as generally safe and well-tolerated across all tested doses, ranging from 0.5 mg/kg to 22.5 mg/kg. At this time, a maximum tolerated dose has not been established. The pharmacokinetic and pharmacodynamic results demonstrated dose-proportional pharmacokinetics, a half-life of 9 to 11 days, no detection of antidrug antibodies in a variety of heavily pretreated solid tumors across tested dose levels.

"Deprioritizing the PYX-106 clinical program as a monoclonal antibody represents a strategic and judicious use of our resources, allowing us to focus on advancing PYX-201," said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. "We are excited about the potential of PYX-201, an innovative, first-in-concept ADC uniquely designed to target the tumor extracellular matrix. The positive preliminary PYX-201 Phase 1 data we presented last month reinforces our confidence in the promise of this program, particularly in addressing unmet needs in HNSCC in both monotherapy and combination therapy settings."

Financial Outlook
The Company's current cash position is expected to fund its planned monotherapy and combination therapy trials of PYX-201 into the second half of 2026.

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. PYX-201, an antibody-drug conjugate (ADC) that uniquely targets EDB+FN, a non-cellular structural component of the tumor extracellular matrix, is being evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors. Pyxis Oncology's therapeutic candidates are designed to directly kill cancer cells and to address factors in the microenvironment that enable the uncontrolled proliferation and immune evasion of malignant tumors. Pyxis Oncology's ADC and immuno-oncology (IO) programs employ novel and emerging strategies to target a broad range of solid tumors resistant or refractory to current standards of care.

To learn more, visit www.pyxisoncology.com or follow us on X (formerly known as 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. All statements other than statements of historical facts contained in this presentation and press release, including without limitation statements regarding the Company's plans to develop, manufacture and commercialize its product candidates, including PYX-201; initial results, timing and progress of the Company's ongoing clinical trials; the expected results of the Company's clinical trials including those of PYX-201 and PYX-106; the expected benefits of the pipeline prioritization; the ability of initial and topline clinical data to de-risk PYX-201 and be confirmed with clinical trial progression, including the safety, tolerability, and potential efficacy of PYX-201 and PYX-106; the potential differentiation, advantage or effectiveness of PYX-201 compared to other approved products or products in development; the dosage and treatment potential of PYX-201; 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 candidates; and the Company's ability 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. Factors that could cause or contribute to 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 Quarterly Report on Form 10-Q filed with SEC on November 12, 2024, 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.

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