Pyxis Oncology Initiates New PYX-201 Combination Trial and Initiates Cohort Expansions of Ongoing Monotherapy Trial

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- Initiation of Phase 1/2 combination trial with PYX-201, an extracellular ADC targeting Extradomain-B Fibronectin (EDB+FN) and Merck's KEYTRUDA® (pembrolizumab) in multiple solid tumors

- Phase 1 monotherapy trial expanded to include cohorts in recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC)

- Ongoing commitment to innovative cancer therapies for patients with limited treatment options

BOSTON, Feb. 04, 2025 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today announced significant progress in its clinical program for PYX-201, a first-in-concept antibody-drug conjugate (ADC) that uniquely targets Extradomain-B Fibronectin (EDB+FN), a non-cellular structural component within the tumor extracellular matrix (ECM), which is highly expressed in various tumor types.

Two PYX-201 trials are now actively recruiting and are designed to evaluate PYX-201 as monotherapy in patients with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) and PYX-201 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with R/M HNSCC and other advanced solid tumors. The combination trial is part of a recently announced Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada).

The Phase 1/2 combination study, PYX-201-102, is now actively recruiting and is on track to initiate dosing patients in Q1 2025 as planned. This Pyxis Oncology sponsored trial is investigating the novel extracellular targeting ADC PYX-201 in combination with pembrolizumab in multiple indications including but not limited to:

- First-line (1L) and second line + (2L+) R/M HNSCC
- Hormone receptor-positive (HR+) and human epidermal growth factor receptor 2 negative (HER2- BC) breast cancer
- Advanced or metastatic triple-negative breast cancer (TNBC)

"PYX-201 is designed to specifically deliver its AUR-0101 payload within the tumor microenvironment (TME) and has been shown to induce immunogenic cell death. When combined with pembrolizumab, PYX-201 may have the potential to enhance the oncologic responses observed with pembrolizumab, by allowing activated T cells to infiltrate TMEs that are often inaccessible and inhospitable," said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. Dr. Sullivan continued, "Treatment options for many patients with advanced solid tumors remain limited, and we are eager to explore this promising therapeutic approach."

In addition, the Part 2 monotherapy expansion cohorts of the ongoing Phase 1 PYX-201-101 study have begun enrolling patients. The expansion phase includes the following cohorts across sites in the US, EU and other countries:

- PYX-201 monotherapy for 2L and third line (3L) R/M HNSCC patients who have received prior platinum and PD-1 inhibitor therapy
- PYX-201 monotherapy for 2L and 3L R/M HNSCC patients who have received prior EGFR and PD-1 inhibitor therapy

Pyxis Oncology is committed to delivering innovative therapies for cancer patients with limited treatment options. These ongoing trials represent a critical step forward in advancing PYX-201 as a potential breakthrough treatment for a broad range of cancers.

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

About PYX-201-101 Clinical Study
PYX-201-101 (NCT05720117) is an ongoing Phase 1 dose escalation (Part 1) and dose expansion (Part 2) study evaluating PYX-201 monotherapy in participants with advanced solid tumors predicted to express EDB+FN, an extracellular matrix protein that is highly expressed in tumor stroma across several human cancer types.

About PYX-201-102 Clinical Study
PYX-201-102 (NCT06795412) is a Phase 1/2, open-label, global, multicenter, dose-escalation and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of PYX-201 in combination with pembrolizumab in participants with advanced solid tumors. Patients with histologically or cytologically confirmed advanced solid tumors, including first-line (1L) R/M head and neck squamous cell carcinoma (HNSCC), advanced or metastatic triple-negative breast cancer (TNBC), hormone receptor-positive (HR+) and human epidermal growth factor receptor 2 negative breast cancer (HER2- BC), gastric cancer (GC), cervical cancer, and second-line and higher (2L+) R/M HNSCC are eligible to enroll.

About PYX-201
PYX-201, an antibody-drug conjugate (ADC) with a microtubule inhibitor (optimized auristatin) payload that uniquely targets Extradomain-B Fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix (ECM), is the company's lead clinical drug candidate.

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. 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 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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