Pyxis Oncology Announces Favorable Preliminary PYX-201 Clinical Phase 1 Part 1 Data

November 20, 2024

— PYX-201 achieved a confirmed 50% ORR by RECIST 1.1 including one Complete Response and 100% Disease Control Rate in six heavily pretreated HNSCC patients, supporting differentiated mono and front-line combo therapy expansion trials to begin dosing 1Q25

—Overall, 26% ORR across all six Solid Tumor Types of Interest (n=31) with Dose Dependent Responses Observed, Supporting First-In-Concept Mechanism with Novel Extracellular Targeting ADC

—New Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada) to evaluate the combination of novel extracellular PYX-201 ADC and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) to begin dosing 1Q25 in patients with HNSCC, HR+/HER2- breast, TNBC, and sarcoma

—PYX-201 generally well-tolerated with a favorable safety profile

—Multiple data updates expected in 2025

—Company to host in-person and virtual investor event today at 4:30 p.m. ET

BOSTON, Nov. 20, 2024 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical stage company focused on developing next generation therapeutics to target difficult-to-treat cancers, today announced positive preliminary data from the ongoing Phase 1 clinical dose escalation study evaluating PYX-201 in multiple types of solid tumors. PYX-201, the Company's lead clinical drug candidate, is 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 (ECM).

"These positive data represent a significant milestone for Pyxis Oncology as our novel ECM-targeting ADC, PYX-201, has demonstrated clinical responses by RECIST 1.1 in six tumor types of interest: HNSCC, ovarian, NSCLC, HR+/HER2- breast, TNBC, and Sarcoma. The breadth and depth of our clinical responses clearly indicate the potential of PYX-201 to provide meaningful clinical benefits to patients with difficult-to-treat cancers," said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. "In addition to the monotherapy expansion studies we are launching in 1Q25 in HNSCC, I am thrilled to announce our new Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada) to evaluate the combination of PYX-201 and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with HNSCC, HR+/HER2- breast, TNBC and Sarcoma with first patients expected to dose in 1Q25."

In this ongoing open-label, multicenter, dose-escalation Phase 1 trial of PYX-201, 80 patients have been enrolled and dosed across multiple solid tumor types to receive doses of PYX-201 ranging from 0.3 mg/kg up to 8.0 mg/kg. The trial's main objectives are to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of PYX-201. The current identified dose range for PYX-201 is 3.6 mg/kg to 5.4 mg/kg. The number of prior lines of cancer therapies for patients enrolled is a median of 4 lines and up to 10 lines in some patients. The data cutoff date for this data announcement was October 4, 2024.

Preliminary Phase 1 Clinical Response Data in Patients with Head and Neck Squamous Cell Carcinoma (HNSCC):

Significant clinical responses were observed in HNSCC. Among evaluable HNSCC patients treated at an identified dose range of PYX-201 from 3.6 – 5.4 mg/kg (n=6), a confirmed 50% objective response rate (ORR) was observed, including one confirmed complete response (CR) and two confirmed partial responses (PR) by RECIST 1.1.

"These encouraging preliminary clinical data demonstrate the potential for PYX-201 to yield meaningful responses in heavily pretreated patients with head and neck cancer along with several additional solid tumor types," said Glenn J. Hanna, M.D., Director, Center for Cancer Therapeutic Innovation (Early Drug Development Program) and Center for Salivary and Rare Head and Neck Cancers at Dana-Farber Cancer Institute, and Associate Professor of Medicine, Harvard Medical School. "The patients in the study have endured multiple rounds of therapy before treatment with PYX-201. We believe the quantity and quality of the responses, including a complete response and PYX-201's tolerability profile, highlight its promising potential across multiple indications with high unmet medical need, particularly in head and neck cancer."

Clinical Trial Collaboration Agreement with Merck's KEYTRUDA® (pembrolizumab)

The Company additionally announces that it has entered into a Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada), for a Pyxis Oncology-sponsored study of PYX-201 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with 1L and 2L head and neck squamous cell carcinoma (HNSCC), HR+/HER2- breast cancer, and triple-negative breast cancer (TNBC) and sarcoma.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. Pyxis Oncology and Merck each retain all commercial rights to their respective compounds, including as monotherapy or as combination therapies.

PYX-201 Development Plans in Head and Neck Squamous Cell Carcinoma (HNSCC)

The Company expects to initiate the following HNSCC Phase 1 expansion studies:

- PYX-201 and KEYTRUDA® combination dose escalation and expansion study in 1L and 2L HNSCC with preliminary clinical data readout expected in the second half of 2025;
- PYX-201 monotherapy study in 2L and 3L HNSCC patients who are platinum and PD-1 inhibitor experienced, with preliminary clinical data readout expected in the second half of 2025; and
- PYX-201 monotherapy study in 2L and 3L HNSCC patients who are EGFR and PD-1 inhibitor experienced, with preliminary clinical data readout expected in first half of 2026.

Preliminary Phase 1 Clinical Response Data in Additional Solid Tumor Types:

Encouraging confirmed and unconfirmed responses were observed in five additional solid tumor types: ovarian cancer, non-small cell lung cancer (NSCLC), HR+/HER2- breast cancer, triple-negative breast cancer (TNBC), and sarcoma.

PYX-201 Development Plan in Additional Tumor Types

Exploratory PYX-201 Phase 1 monotherapy expansion cohorts are planned in ovarian cancer, NSCLC, HR+/HER2- breast cancer, TNBC, and sarcoma, with preliminary clinical data expected in the second half of 2025.

The Company also expects to initiate the following clinical combination studies:

- PYX-201 and KEYTRUDA® combination study in HR+/HER2- breast cancer, TNBC, and sarcoma with preliminary clinical data expected in the second half of 2025 and the first half of 2026.
- Preclinical studies of PYX-201 in combination with other agents in ovarian cancer and NSCLC to commence in 2025 to be followed by clinical studies with preliminary clinical data expected in 2026.

Summary of Preliminary Phase 1 Safety and Pharmacokinetics (PK) Data:

PYX-201 demonstrated favorable preliminary tolerability profile data with low incidence of dose discontinuation, interruptions or delays due to treatment-related adverse events (TRAE). Low incidence of Grade 3 or Grade 4 payload-related TRAEs within the identified dose range reinforce PYX-201's differentiated construct enabling enhanced molecular stability and differential expression of Extradomain-B (EDB) in tumor tissue with negligible expression in normal tissues. The low incidence of Grade 1 or Grade 2 adverse events points to an attractive safety, given that it has been well tolerated and suitable for both monotherapy and combination therapy development.

With respect to PK data, PYX-201 demonstrated increased stability in circulation, which we believe is due to its proprietary design of site-specific conjugation chemistry as compared to certain approved val-cit-monomethyl auristatin E (MMAE) ADCs with non-site-specific conjugation chemistry.

"PYX-201 is an innovative investigational therapy designed with a unique extracellular mechanism of action, unlike any other ADC currently on the market or in development. These initial clinical data, demonstrating tumor shrinkage across a broad range of solid tumors with a differentiated safety profile indicate a significant opportunity to further develop PYX-201 across a variety of tumor types in both the mono and combo therapy settings," said Anthony Tolcher, M.D., FRCPC, FACP, Founder and Chief Executive Officer of NEXT Oncology and PYX-201 Study Investigator. "Additionally, the encouraging safety data support the potential for PYX-201 to be safely combined with other agents, including checkpoint inhibitors, to drive further patient responses."

Additional details and analyses beyond what have been included in this press release will be presented during the Company's preliminary PYX-201 Phase 1 data investor event today.

In-person and Virtual Investor Event Information

Pyxis Oncology will host a virtual and in-person investor event to discuss the preliminary Phase 1 data today, Wednesday, November 20, 2024, at 4:30 p.m. ET at Venue 42 by Convene, located at 5 Times Square in New York City. Anyone interested in attending the live event should RSVP to pyxis.oncology.data.event.

Pyxis Oncology's members of executive management team will be joined by the following physician thought leaders to discuss preliminary data from the Phase 1 trial:

- Anthony Tolcher, M.D., FRCPC, FACP, Founder and Chief Executive Officer, NEXT Oncology
- Glenn J. Hanna, M.D., Director, Center for Cancer Therapeutic Innovation (Early Drug Development Program) and Center for Salivary and Rare Head and Neck Cancers at Dana-Farber Cancer Institute, and Associate Professor of Medicine, Harvard Medical School

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 mono and combination therapies. PYX-201, an antibody-drug conjugate (ADC) that uniquely targets EDB+FN, a non-cellular structural component of the tumor extracellular matrix, and PYX-106, a fully human Siglec-15-targeting antibody designed to block suppression of T-cell proliferation and function, are being evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors. Pyxis Oncology's therapeutic candidates are designed to directly kill tumor cells and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. Pyxis Oncology's ADC and immuno-oncology (IO) programs employ novel and emerging strategies to target a broad range of solid tumors resistant 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 contain 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; 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; 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.

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