Pyxis Oncology Announces Dosing of First Subject in Phase 1 Trial of PYX-201, a Novel ADC for Solid Tumors

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Milestone marks transition of Pyxis Oncology to a clinical-stage company

Preliminary data anticipated in early 2024

CAMBRIDGE, Mass., March 16, 2023 (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 dosing of the first subject in a Phase 1 trial of PYX-201. PYX-201 is a novel antibody-drug conjugate (ADC) product candidate licensed from Pfizer targeting extradomain-B (EDB) of fibronectin, a non-internalizing antigen, that is an integral component of the extracellular matrix in tumors. EDB fibronectin is overexpressed in many solid tumors and minimally expressed in most normal adult tissues. The Company anticipates preliminary data from this trial in early 2024.

“PYX-201 has the potential to offer a new approach to targeting multiple tumor types via a multipronged mechanism of action that may benefit patients with solid tumors. We expect to see preliminary data from this study, including biomarker results and potential early signs of clinical activity, in early 2024,” said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. “I’m proud of the work done by the Pyxis Oncology team to initiate dosing in our first clinical trial. Dosing is a significant achievement and important milestone that marks the transition of Pyxis Oncology to a clinical-stage company.”

Alexander Spira, M.D., Director NEXT Oncology Virginia, Co-Director, VCS Research Institute, and Director, Thoracic and Phase I Program and Clinical Assistant Professor at Johns Hopkins University, said, "We are always looking for potential new treatments for patients who have limited or no options available. I am particularly excited about PYX-201 because it was designed to offer several important safety and efficacy improvements compared to traditional ADCs, and we look forward to evaluating it in this Phase 1 study.”

The Phase 1 trial, referred to as PYX-201-101, is an open-label, multicenter, dose-escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of PYX-201 and identify recommended doses for further study. Patients with relapsed or refractory solid tumors, including non-small cell lung cancer (NSCLC), hormone receptor-positive breast cancer, ovarian cancer, thyroid cancer, pancreatic ductal adenocarcinoma, soft tissue sarcoma, hepatocellular carcinoma or kidney cancer are eligible to enroll.

Jay Feingold, M.D., Ph.D., Chief Medical Officer of Pyxis Oncology, said, “ADCs are important tools in the cancer treatment armamentarium, and further ADC development may represent a significant opportunity to address several solid tumor types with significant unmet need.”

Jan Pinkas, Ph.D., Chief Scientific Officer of Pyxis Oncology, added, “Unlike traditional ADCs, PYX-201 acts via three distinct mechanisms to comprehensively target tumors independent of cell surface marker expression. Once PYX-201 binds to EDB fibronectin in the tumor stroma, a potent auristatin-derived payload is cleaved and diffuses across adjacent tumor cell membranes and surrounding supportive tumor infrastructures, including fibroblasts and tumor vasculature. PYX-201 also acts via a bystander effect in the tumor microenvironment as aur0101 payload is recycled and re-released, directly killing adjacent tumor cells. Finally, PYX-201 also stimulates anti-tumor immunogenic activity by promoting dendritic cell maturation and inducing immunogenic cell death, which could provide a rationale for the evaluation of combination-based approaches with immuno-oncology products, including checkpoint inhibitors.”

About the Flexible Antibody Conjugation Technology (FACT) Platform
The FACT platform, licensed from Pfizer, Inc. in 2021, is designed to facilitate creation of next-generation ADCs like PYX-201 that have the potential for improved anti-tumor activity, safety and tolerability. Compared to traditional ADC approaches, the FACT platform is based upon technical improvements to allow site-specific payload conjugation, linker stability and payload potency.

About PYX-201-101
PYX-201-101 (NCT05720117) is an open-label, multicenter, Phase 1 dose-escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of PYX-201. Patients with relapsed or refractory solid tumors known to have significant expression of EDB of fibronectin, including with relapsed or refractory solid tumors, including non-small cell lung cancer, hormone receptor positive breast cancer, ovarian cancer, thyroid cancer, pancreatic ductal adenocarcinoma, soft tissue sarcoma, hepatocellular carcinoma or kidney cancer are eligible to enroll.

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. 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 antibody-drug conjugates (ADCs) 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 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 1, 2022, and in our other filings with the SEC. 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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