Pyxis Oncology Announces FDA Clearance of Two IND Applications

December 1, 2022

FDA grants IND clearances of PYX-201, a novel antibody-drug conjugate (ADC) product candidate, *and PYX-106, an immunotherapy product candidate*

Phase 1 clinical trials of PYX-201 and PYX-106 will evaluate the safety and anti-tumor activity in patients with select solid tumors

Dual IND clearances represent achievement of significant 2022 milestones and executional pipeline advancement

Cash runway extended into first half 2025

CAMBRIDGE, Mass., Dec. 01, 2022 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical stage company focused on developing next-generation therapeutics to target difficult-to-treat cancers, announced today that it has received clearance for its two Investigational New Drug (IND) applications from the U.S. Food and Drug Administration (FDA) to initiate Phase 1 clinical trials. PYX-201, a novel antibody-drug conjugate (ADC) product candidate, will be investigated for the potential treatment of several solid tumors, including breast, head and neck, lung, and thyroid cancer. PYX-106, an immunotherapy product candidate, will be investigated for the potential treatment of solid tumors, including bladder, cholangio-carcinoma, colorectal, and kidney cancer.

“We are thrilled to receive two nearly simultaneous IND clearances from the FDA, representing a major moment as we transition to a clinical stage company demonstrating the operational prowess of our team,” said Lara Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. “We are proud of both the substantial clinical IND execution capabilities of our organization and the recent expansion of exclusivity of our ADC technology toolkit with Pfizer, both of which solidify Pyxis Oncology as a leading emerging clinical company. We believe the combination of our veteran leadership team and our cash runway into the first half of 2025 positions us to advance these potentially important therapies for patients who desperately need new options.”

Jay Feingold, M.D., Ph.D., Chief Medical Officer of Pyxis Oncology, added, "We are excited to advance multiple programs to the clinic. Both product candidates could potentially be applied to a broad range of tumors and address a significant need in the community. PYX-201 represents a new potential class of ADCs with a multifaceted mechanism of action which targets a component of the tumor microenvironment that is highly expressed in a variety of solid tumors. In patient-derived xenograft (PDX) model studies of NSCLC and pancreatic cancer, the ADC delivered a highly potent payload that was shown to attack the tumor and associated cells directly in a dose-dependent manner. PYX-106 is a potential immunotherapy that has demonstrated strong activity in preclinical studies and binds to an immune-regulatory receptor, Siglec-15, that has been shown to have an immune suppressive function and shares little overlap with the most prominent IO targets, the PD-1/PDL-1 pathway. The antibody's strong activity and its target's unique expression suggest that PYX-106 could be valuable in both mono and combination treatment settings for a broad range of tumors. We look forward to beginning both clinical trials in early 2023."

About PYX-201-101
The first-in-human trial of PYX-201 will be a dose escalation trial to determine the recommended phase 2 dose. The study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy in patients with solid tumors known to have significant expression of EDB of fibronectin.

About PYX-106-101
The first-in-human trial of PYX-106 will be a dose escalation trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy in patients with tumors known to have significant infiltration of M2 macrophages and expression of Siglec-15 in order to determine the recommended phase 2 dose.

About PYX-201
PYX-201 is a non-internalizing ADC product candidate that binds to extradomain-B (EDB) fibronectin, an integral component of the extracellular matrix in the tumor that is overexpressed in many malignancies and is minimally expressed in most normal adult tissues. As shown in patient-derived xenograft (PDX) model studies of NSCLC and pancreatic cancer, its highly cell-permeable auristatin payload is enzymatically released after binding, which directly attacks cancer cells and other components that form the supportive tumor infrastructure. Auristatin elicits an antitumor immune response by inducing immunogenic cell death and dendritic cell maturation. While its effects are primarily due to its non-internalizing activity, a fraction of PYX-201 may also be internalized, further enhancing its antitumor activity.

About PYX-106
PYX-106 is an immunotherapy product candidate in development that blocks the activity of Siglec-15, an emerging immune suppressor expressed across a broad range of tumors. Siglec-15 expression does not overlap with one of the most common targets in immuno-oncology, PD-1, supporting its potential use alone and in combination with current immunotherapies. PYX-106 may benefit patients who do not respond to current standards of care. In preclinical studies, PYX-106 has demonstrated broad immune activation, strong binding affinity, and a 7-day half-life. Cumulatively, these advantages may translate to superior anticancer activity and more flexible dosing regimens.

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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