Pyxis Oncology Granted FDA Fast Track Designation for PYX-201 Monotherapy in Patients with Recurrent or Metastatic Head and Neck Cancer

February 26, 2025

Designation applies to the treatment of adult patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 antibody

BOSTON, Feb. 26, 2025 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to PYX-201 for the treatment of adult patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 antibody. PYX-201 is 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.

“Receiving Fast Track designation for PYX-201 from the FDA marks a significant milestone for Pyxis Oncology, recognizing our potential to address the significant medical need in R/M HNSCC. This designation underscores the urgency of bringing differentiated treatment options to patients and will help accelerate the development of PYX-201 as we actively recruit patients for our trial,” said Lara S. Sullivan, M.D., President and Chief Executive Officer. “We look forward to working with the FDA to advance this promising therapy as efficiently as possible.”

Fast Track designation is an FDA program intended to facilitate and expedite the development and review of new drugs in the U.S. for the treatment of a serious or life-threatening condition. To qualify for this designation, there must be clear data demonstrating the drug has potential to address unmet medical need in the designated condition.

About Head and Neck Squamous Cell Carcinoma (HNSCC)

Head and Neck Cancer (HNC) is the sixth most common cancer in the world, with 1,464,550 new cases and 487,993 deaths from HNC globally[1]. Squamous Cell Carcinoma presents as the most common subtype and is derived from the mucosal lining of the oral cavity, pharynx and larynx. Almost 50% of cases progress to recurrent or metastatic cancer post-initial treatment, presenting patients with a median overall survival of less than a year. The overall incidence of HNSCC is expected to rise, with a predicted 30% increase annually by 2030[2]. The increase has been associated with multiple factors, including but not limited to tobacco use, alcohol consumption, a rise in HPV infections, and other environmental catalysts. With limited development outside of immunotherapy in the last decade, HNSCC remains one of the most difficult to treat carcinomas, highlighting the unmet need.

[1] Zhou T, Huang W, Wang X, Zhang J, Zhou E, Tu Y, et al. Global burden of head and neck cancers from 1990 to 2019. iScience. 2024;27:109282 United States; [2]Gormley, M., Creaney, G., Schache, A. et al. Reviewing the epidemiology of head and neck cancer: definitions, trends and risk factors. Br Dent J 233, 780–786 (2022).

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.

Two PYX-201 trials are now actively recruiting. One trial, PYX-201-101, is designed to evaluate PYX-201 as monotherapy in patients with R/M HNSCC. A second trial, PYX-201-102, is evaluating 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).

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

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. PYX-201 is designed to directly kill cancer cells and to address factors in the microenvironment that enable the uncontrolled proliferation and immune evasion of malignant tumors.

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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