Ikena Oncology Receives FDA Fast Track Designation for Novel AHR Antagonist IK-175 in Combination with Immune Checkpoint Inhibitors to Treat Urothelial Carcinoma

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BOSTON, March 06, 2023 (GLOBE NEWSWIRE) -- Ikena Oncology, Inc. (Nasdaq: IKNA, “Ikena”), a targeted oncology company forging new territory in patient-directed cancer treatment, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for IK-175, the Company’s novel aryl hydrocarbon receptor (AHR) antagonist, in combination with immune checkpoint inhibitors in patients with advanced urothelial carcinoma who have progressed on or within three months of receiving the last dose of checkpoint inhibitors.

Fast Track designation is reserved for therapies that represent potential best-in-class therapeutic options for diseases with high unmet need. Therapies that receive Fast Track designation often have the opportunity to communicate more frequently with the FDA on trial design and data and may also be eligible for priority review and accelerated approval. IK-175 is the second of Ikena’s candidates to receive Fast Track designation; the FDA has also granted the designation to IK-930, the Company’s novel TEAD inhibitor, in patients with unresectable NF2-deficient malignant pleural mesothelioma.

“There is an urgent need for new treatment options for urothelial carcinoma patients, many of whom find themselves out of options after progressing on checkpoint inhibitors. The Fast Track designation for IK-175 reflects the FDA’s interest in the potential role of our AHR antagonist to overcome the development of resistance to checkpoint inhibitors and supports our strategy of combining IK-175 with nivolumab to expand the number of cancer patients that can benefit from immunotherapy,” said Sergio Santillana, MD, Chief Medical Officer at Ikena.

IK-175 targets AHR, a compelling cancer-driving transcription factor that prevents immune recognition in a multitude of cancers by modulation of innate and adaptive immunity. Patients with urothelial carcinoma are generally treated through a combination of standard-of-care options, including surgery, chemotherapy, radiation and immunotherapies, including checkpoint inhibitors.

IK-175 is currently being studied in a Phase 1a/b clinical trial as a monotherapy and in combination with nivolumab in patients with advanced or metastatic solid tumors including urothelial carcinoma for which standard therapy is no longer effective or is intolerable (NCT04200963, or IK-175-001). Initial clinical data presented at the Society for Immunotherapy of Cancer (SITC) 2022 Annual Meeting demonstrated that IK-175 is well tolerated and showed encouraging, durable, anti-tumor activity in stage 1 of the trial’s monotherapy and combination arms in urothelial carcinoma patients. The IK-175 program is being developed in collaboration with Bristol Myers Squibb and they have an option to exclusively license the program through early 2024.

About Ikena Oncology
Ikena Oncology™ is focused on developing differentiated therapies for patients in need that target nodes of cancer growth, spread, and therapeutic resistance in the Hippo and RAS onco-signaling network. The Company’s lead targeted oncology program, IK-930, is a paralog-selective TEAD inhibitor addressing the Hippo signaling pathway, a known tumor suppressor pathway that also drives resistance to multiple targeted therapies. The Company’s additional research spans other targets in the Hippo pathway as well as the RAS signaling pathway, including developing IK-595, a novel MEK-RAF inhibitor. Additionally, IK-175, an AHR antagonist, is being developed in collaboration with Bristol Myers Squibb. Ikena aims to utilize their depth of institutional knowledge and breadth of tools to efficiently develop the right drug using the right modality for the right patient. To learn more, visit www.ikenaoncology.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding: the timing and advancement of our targeted oncology programs, including the timing of updates; our expectations regarding the therapeutic benefit of our targeted oncology programs; our ability to efficiently discover and develop product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the implementation of our business model, and strategic plans for our business and product candidates. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of our targeted oncology programs; our expectations regarding the therapeutic benefit of our targeted oncology programs; expectations regarding our new executive officer; our ability to efficiently discover and develop product candidates; the implementation of our business model, and strategic plans for our business and product candidates, and other factors discussed in the “Risk Factors” section of Ikena’s Form 10-Q for the quarter ended September 30, 2022, which is on file with the SEC, as updated by any subsequent SEC filings. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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