Ikena Oncology Receives FDA Fast Track Designation for Novel TEAD Inhibitor IK-930 to Treat Unresectable NF2-Deficient Mesothelioma

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BOSTON, June 22, 2022 (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-930, the Company’s novel TEAD inhibitor targeting the Hippo signaling pathway, in patients with unresectable NF2-deficient malignant pleural mesothelioma (MPM).

Fast Track designation granted by FDA facilitates the development and expedites the review of drugs intended to treat serious or life-threatening diseases. Features of Fast Track designation include opportunities for more frequent interactions with the FDA review team and, if supported by clinical data, the therapy could potentially be eligible for priority review. Earlier in 2022, the FDA granted IK-930 Orphan Drug designation, which supports development of drugs for rare disorders, as a potential novel therapeutic option for patients with malignant pleural mesothelioma.

“We are delighted to announce that IK-930 has been granted Fast Track designation, demonstrating the potential of IK-930 to address the unmet medical need of people with unresectable NF2-deficient MPM,” said Sergio Santillana, MD, Chief Medical Officer at Ikena. “This milestone, combined with the Orphan Drug designation in mesothelioma, further validates our targeted oncology approach to address significant unmet medical needs for difficult-to-treat cancers and supports our goal to advance the development of IK-930 for the patients who potentially could benefit most.”

IK-930 binds to TEAD transcription factors to prevent transcription of multiple genes in the Hippo pathway that are known to cause cancer progression. Patients with NF2-deficient malignant pleural mesothelioma account for approximately 40% of mesothelioma patients worldwide and are generally treated through a combination of standard-of-care options, including surgery, chemotherapy, immunotherapy, and radiation. IK-930 provides a novel targeted approach to address the underlying biology driven by the genetic alterations that cause cancer pathogenesis.

IK-930 is currently being studied in a Phase 1 clinical trial as a monotherapy in patients with advanced solid tumors with or without gene alterations in the Hippo pathway, including NF2-deficient malignant mesothelioma, Epithelial Hemangioendothelioma (EHE) with documented TAZ/CAMTA1 fusion genes as well as other solid tumors with either NF2 deficiency or with YAP/TAZ genetic fusions (NCT05228015). Preclinical and translational data shared at the American Association for Cancer Research 2022 Annual Meeting highlighted IK-930 as a potential first-in-class TEAD inhibitor that could address unmet need and overcome therapeutic resistance.

About Ikena Oncology
Ikena Oncology™ is focused on developing novel therapies targeting key signaling pathways that drive the formation and spread of cancer. The Company’s lead targeted oncology program, IK-930, is a TEAD inhibitor addressing the Hippo signaling pathway, a known tumor suppressor pathway that also drives resistance to multiple targeted therapies. The Company’s ongoing discovery research spans the Hippo pathway as well as the RAS signaling pathway. Additional programs targeting the tumor microenvironment and immune signaling are in the clinic, including IK-175, an aryl hydrocarbon receptor antagonist, which is being developed in collaboration with Bristol Myers Squibb. Ikena’s pipeline is built on addressing genetically defined or biomarker-driven cancers and developing therapies that can serve specific patient populations in need of new therapeutic options. 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, implied and express statements regarding Ikena’s strategy, business plans and focus; and the progress of the preclinical and clinical development of the programs in Ikena’s portfolio. 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 associated with the following: the impact of the ongoing COVID-19 pandemic on countries or regions in which Ikena has operations or does business, as well as on the timing and anticipated results of its clinical trials, strategy and future operations, the therapeutic potential of Ikena’s product candidates and the timing and completion of its clinical trials and related data analyses; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies, Ikena’s ability to fund its research and development efforts, and other factors discussed in the “Risk Factors” section of Ikena’s Annual Report on Form 10-K for the year ended December 31, 2021, which is on file with the SEC, as updated by any subsequent SEC filings. Any forward-looking statements contained in this press release speak only as of the date hereof, and Ikena expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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