



Ikena Oncology Announces New Program in Next-Generation MEK-RAF Inhibition and Provides Corporate Update

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Novel best-in-class MEK-RAF complex inhibitor IK-595 targets RAS pathway; IND in 2023

Novel paralog-selective TEAD inhibitor IK-930 advancing as planned in dose escalation; clinical data in 2023

Company prioritizes advancement of targeted oncology portfolio; cash runway extended into 2025

BOSTON, Nov. 28, 2022 (GLOBE NEWSWIRE) -- Ikena Oncology, Inc. (Nasdaq: IKNA, "Ikena"), a targeted oncology company forging new territory in patient-directed cancer treatment, today announced a next-generation mitogen-activated protein kinase (MEK)-RAF complex inhibitor, IK-595, has been nominated as the company's first development candidate in the RAS pathway.

The RAS pathway is implicated in at least half a million new cancer diagnosis each year in the United States alone. Ikena aims to target the pathway on multiple levels, including preventing known resistance mechanisms to achieve deep and sustained responses. Ikena's new development candidate, IK-595, traps MEK and RAF in an inactive complex, more completely inhibiting RAS signals than existing inhibitors. IK-595's ability to complex CRAF, in particular, prevents a well-recognized signaling bypass mechanism that cancer cells employ to drive therapeutic resistance to other drugs in this class. In addition, trapping CRAF in an inactive complex prevents the kinase independent anti-apoptotic function in RAS and RAF mutant cancers, a mechanism that cannot be addressed with first generation MEK inhibitors or pan-RAF inhibitors. IK-595 is being developed as an oral therapy, with a half-life enabling a pharmacokinetic profile potentially superior to other drugs, with the goal of developing an optimal therapeutic window for patients. The company plans to submit an investigational new drug application (IND) for IK-595 to the US Food & Drug Administration (FDA) in the second half of 2023.

"I am thrilled to announce this addition to our pipeline, one that adds to our holistic approach to the Hippo & RAS oncosignaling network. IK-595 inhibits multiple nodes of MEK-RAF signaling, including avoiding known mechanisms of resistance," said Mark Manfredi, PhD, Ikena's Chief Executive Officer. "The industry's excitement about MEK inhibition stems from its great potential as a target, but the challenges of CRAF bypass and achieving optimal target inhibition have kept first generation treatments from meeting the full potential of the target. We are hopeful that our MEK-RAF trapping approach with an optimized therapeutic window can make IK-595 a game-changing candidate for multiple indications in the RAS space."

Development Highlights, Corporate Updates, and Upcoming Milestones

- Advancing new development candidate, IK-595, through IND-enabling studies, targeting MEK-RAF through novel mechanisms aiming to address existing gaps in the MEK inhibitor space
 - Preclinical differentiation data planned for presentation in the first half of 2023
 - IND targeted in the second half of 2023
- Progressing novel, paralog-selective transcriptional enhanced associate domain (TEAD) inhibitor, IK-930, in the clinic and further defining differentiation profile from panTEAD inhibition
 - Monotherapy program progressing as planned, advanced through multiple dose escalation cohorts
 - Preclinical data on differentiation and advantages of paralog selectivity planned for presentation in first half of 2023
 - Initiation of osimertinib combination cohort clinical program expected in first half of 2023
 - Initial clinical data from IK-930 monotherapy program expected in second half of 2023
- Following a portfolio review, discontinuing the internal clinical development of the EP4 antagonist IK-007 and exploring strategic alternatives for this program
 - Clinical data from IK-007 in microsatellite stable colorectal cancer (MSS-CRC) will be presented in a poster at 2022 European Society for Medical Oncology Immuno-Oncology Congress
- Portfolio reprioritization and streamlining of discovery and clinical activities contribute to extension of cash runway into 2025
 - Runway does not include any potential licensing revenue from the aryl hydrocarbon receptor (AHR) antagonist IK-175 program, currently in development in collaboration with Bristol Myers Squibb and eligible for opt-in through early 2024

"Ikena has a strong track record of internal drug discovery and development that has built our robust clinical and early-stage pipeline," said Jotin Marango, MD, PhD, Chief Financial Officer and Head of Corporate Development of Ikena. "Our goal is to continue our leadership in targeted oncology by discovering and advancing best-in-class candidates like IK-930 and IK-595, therapies designed to address the needs of specific patient populations while at the same time building value for our shareholders."

About Ikena Oncology

Ikena OncologyTM 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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