

# Ikena Oncology Reports First Quarter 2023 Financial Results and Highlights Advancements Across Targeted Oncology Pipeline

May 15, 2023

Lead targeted oncology program in Hippo pathway, IK-930, continues to advance through dose escalation with no dose-limiting toxicities observed to-date

Preclinical data at AACR Annual Meeting demonstrated IK-930 TEAD1 selectivity with equivalent activity to panTEAD inhibition and significantly improved therapeutic index

Differentiated MEK-RAF complex inhibitor profile of IK-595 presented at AACR Special Conference on Targeting RAS

Underwritten offering of \$40M extends runway into 2026

BOSTON, May 15, 2023 (GLOBE NEWSWIRE) -- Ikena Oncology, Inc. (Nasdaq: IKNA, "Ikena", "Company"), a targeted oncology company forging new territory in patient-directed cancer treatment, today announced financial results for the first quarter ended March 31, 2023. The Company also provided an update across the organization and pipeline.

"The start to 2023 has been full of exciting developments, including external clinical validation of the Hippo pathway and targeting TEAD. In addition to this de-risking event, we have been able to highlight our own differentiation in the space with IK-930's unique selectivity profile, optimized therapeutic index, and broad applicability as both a monotherapy and in combination across several patient populations. As we continue to advance in the clinic, our ability to continuously dose patients will allow us to fully explore IK-930's therapeutic potential," commented Mark Manfredi, Ph.D., Chief Executive Officer of Ikena. "The first quarter also was the first time we shared the novel profile of IK-595, our MEK-RAF complex inhibitor. We designed IK-595 to optimize the potential therapeutic window and durably bind the RAFs, focusing on preventing multiple CRAF mechanisms that can cause tumorigenesis. Both of these programs are aiming to serve patient populations in which current approved and experimental therapies are insufficient or failing. That need is driving our entire team to continue delivering on development in the clinic, including the IK-595 IND filing and the initial IK-930 clinical data expected later this year."

# **Summary of Recent Pipeline Progress and Corporate Update**

#### IK-930: TEAD1-Selective Hippo Pathway Inhibitor

- IK-930 revealed as a TEAD1 selective inhibitor with significant advantages in therapeutic index at American Association for Cancer Research (AACR) Annual Meeting in April 2023
  - Multiple preclinical datasets comparing IK-930 to panTEAD inhibition presented, including nonhuman primate tolerability and comparable efficacy in multiple models
  - Data presented demonstrated that the combination of IK-930 and several targeted agents, including EGFR, KRAS G12C, and MEK inhibitors, showed a decrease in the development of drug-resistant persister cells, suggesting the potential of IK-930 to expand the number of patients who could benefit from these targeted therapies
- Initial clinical data from the monotherapy portion of the ongoing Phase 1 clinical trial of IK-930, including patients from the dose escalation cohorts and backfilling, is planned for the fourth quarter of 2023
  - The study continues to progress as planned through dose escalation with no reported dose-limiting toxicities to date
  - The protocol includes backfilling of cohorts at efficacious exposures in patients with NF2-deficient mesothelioma and epithelioid hemangioendothelioma (EHE)
  - The expansion cohorts of the trial will evaluate IK-930 as a monotherapy in these indications, as well as in other
    patients with solid tumors with detectable alterations in the Hippo pathway, including NF2 deficiency and YAP/TAZ
    alterations
- Combination cohorts in the IK-930 clinical program are planned based on emerging pharmacokinetic and pharmacodynamic data from monotherapy dose escalation; osimertinib is the first combination partner through a clinical collaboration with AstraZeneca
  - Preclinical data exemplified the potential of IK-930 in combination with osimertinib in EGFR mutant cancers, both in first line as a resistance-preventative combination and in later lines, post-resistance emergence
  - Additional combinations of IK-930 with MEK inhibitors and KRAS inhibitors have the potential to address resistance to and durability of targeted treatments in RAS mutant cancers

#### IK-595: MEK-RAF Complex Inhibitor

- Data presented at the AACR Special Conference on Targeting RAS demonstrated key differentiation characteristics of IK-595 from first and second generation MEK inhibitors including:
  - IK-595 traps MEK and RAF in an inactive complex to overcome CRAF bypass mechanism and block its kinase-independent activity, more durably and completely inhibiting RAS-MAPK signaling than existing inhibitors
  - The optimization of the half-life of IK-595 can enable dosing schedules to achieve plasma exposure above IC<sub>90</sub> to drive tumor cell killing, while allowing a break from target engagement for normal tissues to recover
- Investigational new drug (IND) application submission for IK-595 planned for the second half of 2023
  - Potential indications for the clinical program are being explored based on IK-595 sensitivity and unmet clinical need; indication models that have shown high sensitivity for IK-595 to date include:
    - NRAS mutant cancers, including melanoma, colorectal cancer, and acute myeloid leukemia
    - KRAS mutant cancers, including non-small cell lung, colorectal and pancreatic cancers, and
    - CRAF altered cancers, which represent an orphan population with a high unmet need and a unique potential to benefit from IK-595's mechanism
  - Additionally, IK-595 has been shown to be active as a monotherapy in many RAF models, including BRAF mutant cancers, and synergistic in combination with other targeted agents, including KRAS G12C, SHP2, SOS1, TEAD, EGFR, PI3K and mTOR inhibitors in various RAS mutant cancer cell lines

#### IK-175: AHR Inhibitor in Collaboration with Bristol Myers Squibb

- In March 2023, the FDA 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
- The Phase 1 clinical trial in urothelial carcinoma has completed enrollment; treatment is ongoing and the program is eligible for opt-in from Bristol Myers Squibb through early 2024

### Corporate Update

- Today the Company announced the pricing of an underwritten offering for estimated gross proceeds of approximately \$40 million
- Together with its existing cash, cash equivalents, and investments, the Company believes that cash at hand will be sufficient to meet its operating requirements into 2026 and will fund additional data events for both IK-930 and IK-595 beyond the initial read outs

# Financial Results for the Quarter Ended March 31, 2023

As of March 31, 2023, Ikena had \$137.8 million in cash, cash equivalents and marketable securities, which does not include proceeds from the recent underwritten offering that priced today.

Collaboration revenue was \$5.3 million and \$3.4 million for the three months ended March 31, 2023 and 2022, respectively. The increase in collaboration revenue was primarily due to the Company's decision to stop the IK-175 head and neck study.

Research and development expenses were \$15.6 million and \$14.3 million for the three months ended March 31, 2023 and 2022, respectively. The increase in research and development expenses of \$1.2 million was primarily related to personnel and overhead costs due to an increase in headcount, partially offset by a decrease in other discovery stage programs, as a result of the Company prioritizing its focus on advancing its clinical stage programs.

General and administrative expenses were \$5.3 million and \$6.0 million for the three months ended March 31, 2023 and 2022, respectively. The decrease in general and administrative expenses of \$0.7 million was primarily attributable to a decrease in legal, consulting, and insurance expenses.

#### **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 TEAD1 selective Hippo pathway inhibitor, 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, implied and express statements regarding: the anticipated use of proceeds from the underwritten offering, statements

regarding the completion of the offering, 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, expectations with respect to cash runway, and strategic plans for our business and product candidates. The words "may," "will," "could," "should," should," should, s "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forwardlooking 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, the sufficiency of the Company's capital resources to fund operating expenses and capital expenditure requirements and the period in which such resources are expected to be available, and other factors discussed in the "Risk Factors" section of Ikena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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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Selected Balance Sheet Items:	March 31, 2023		December 31, 2022	
Cash and cash equivalents	\$	29,329	\$	59,919
Marketable securities	\$	108,484	\$	97,028
Total assets	\$	152,401	\$	172,259
Total liabilities	\$	17,379	\$	25,290
Additional paid-in-capital	\$	363,915	\$	361,915
Accumulated deficit	\$	(228,438)	\$	(214,219)
Total stockholders' equity	\$	135,022	\$	146,969

# Selected Financial Information (in thousands, except share and per share data)

	Three Months Ended March 31,				
Statement of Operations Items:	2023			2022	
Research and development revenue under collaboration agreement	\$	5,313	\$	3,384	
Operating expenses:					
Research and development		15,552		14,343	
General and administrative	5,276			6,003	
Total operating expenses		20,828		20,346	
Loss from operations		(15,515)		(16,962)	
Interest income		730		172	
Other income (expense)		566		(49)	
Total other income, net		1,296		123	
Net loss	\$	(14,219)	\$	(16,839)	
Other comprehensive loss:					
Unrealized gain (loss) on marketable securities		272		(478)	
Total comprehensive loss	\$	(13,947)	\$	(17,317)	
Net loss per share:					
Net loss per share attributable to common stockholders basic and diluted	\$	(0.39)	\$	(0.47)	
Weighted-average common stocks outstanding, basic and diluted		36,257,493		36,075,407	