

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 23, 2024

IKENA ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40287
(Commission
File Number)

81-1697316
(I.R.S. Employer
Identification No.)

Ikema Oncology, Inc.
645 Summer Street, Suite 101
Boston, Massachusetts 02210
(Address of principal executive offices, including zip code)

(857) 273-8343
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	IKNA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On May 23, 2024, the Board of Directors (the "Board") of Ikena Oncology, Inc. (the "Company") approved a plan to discontinue the clinical development of IK-930, continue clinical development of IK-595 and reduce its current workforce by approximately 53% (the "Restructuring Plan"). On May 28, 2024, the Company announced the Restructuring Plan and the Board's approval of a process to explore, review and evaluate a range of potential strategic options.

The Restructuring Plan will result in the termination of approximately 18 employees and is expected to be completed in the third quarter of 2024. Following the Restructuring Plan, the Company expects to have approximately 16 full-time employees.

The Company expects to incur costs related to the Restructuring Plan during the three months ended June 30, 2024 related to employee severance and related termination benefits, which are expected to result in approximately \$1.2 million in cash expenditures.

Item 7.01 Regulation FD Disclosure.

On May 28, 2024, the Company issued a press release announcing the Restructuring Plan. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

On May 28, 2024, the Company updated its corporate presentation, attached as Exhibit 99.2 to this Current Report on Form 8-K. The corporate presentation will also be available in the investor relations section of the Company's website at <https://www.ikenaoncology.com/>.

The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On May 28, 2024, the Company announced the Board's approval of a process to explore, review and evaluate a range of potential strategic options available to the Company, including without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. There can be no assurance of completion of any particular course of action or a defined timeline for completion. The Company does not expect to make further public comment regarding these matters unless and until the Board has approved a specific option or otherwise concludes its review of strategic options.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are based upon current plans, estimates and expectations of management that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "may," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All statements, other than historical facts, including statements regarding the Company's expectations related to the Restructuring Plan and the Board's exploration of strategic options are forward-looking statements. These forward-looking statements are based on management's current expectations. Actual results could differ from those projected in any forward-looking statements due to several risk factors, including but not limited to the important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, and its other filings with the U.S. Securities and Exchange Commission. Any forward-looking statements represent management's estimates as of this date and the Company undertakes no duty to update these forward-looking statements, whether as a result of new information, the occurrence of current events, or otherwise, unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 [Ikena Oncology, Inc. Press Release dated May 28, 2024](#)

99.2 [Ikena Oncology, Inc. Corporate Presentation](#)

104 Cover Page Interactive Data File

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Ikena Oncology, Inc.

Date: May 28, 2024

By: /s/ Mark Manfredi
Mark Manfredi, Ph.D.
President and Chief Executive Officer



Ikena Oncology Announces Strategic Update

Ikena to discontinue development of IK-930

IK-595 dose escalation continues in RAS and RAF mutant cancers; Encouraging PK and PD profile shown to date

Ended first quarter with \$157.3 million; Exploring strategic options to maximize shareholder value

BOSTON, May 28, 2024, – Ikena Oncology, Inc. (Nasdaq: IKNA, “Ikena,” “Company”) today announced discontinuation of the clinical IK-930 program, the Company’s TEAD1- selective Hippo pathway inhibitor and continued clinical development of IK-595, a novel MEK-RAF molecular glue. Concurrently, Ikena is evaluating strategic options for both the Company and its development pipeline.

“Ikena is dedicated to thoughtfully putting our capital to work towards impactful treatments for patients, and in doing so building value for our shareholders. Together with our board of directors, we made the difficult decision to wind down the IK-930 program. Going forward, we believe that IK-930’s profile may enable combination opportunities with other targeted agents through partnerships,” commented Mark Manfredi, Ph.D., Chief Executive Officer of Ikena. “Our MEK-RAF molecular glue, IK-595, continues to progress rapidly in the clinic with encouraging early PK and PD data which supports a potentially differentiated therapeutic index. This is key to treating the broad population of patients suffering from RAS and RAF mutant cancers where other MEK inhibitors have failed.”

Pipeline & Corporate Updates

IK-930: TEAD1-Selective Hippo Pathway Inhibitor

- Based on a review of clinical data to date, available resources, and the Company’s strategic priorities, the Company decided to discontinue development of IK-930
- The IK-930 Phase 1 program will begin winddown activities; treatment will continue for patients enrolled to date who have derived benefit
- The Company will seek strategic options for the program, including potential partners for development of IK-930 in combination with other targeted agents

IK-595: MEK-RAF Molecular Glue

- The first two cohorts in the Phase 1 study of IK-595 in patients with RAS and RAF mutant cancers have cleared; backfilling in select cohorts is planned for the second half of 2024
- Promising early pharmacokinetics (PK) and pharmacodynamics (PD) activity has been observed, with dose dependent exposure and target modulation measured in the blood
 - Reached above 80% pERK inhibition at 4 hours post dosing to date, with above 60% inhibition sustained through 24 hours; dose escalation continues

Corporate Updates

- In connection with the discontinuation of IK-930 development, the Company is executing a workforce reduction of approximately 53%
- \$157 million in cash, cash equivalents and marketable securities as of March 31, 2024
- Concurrently with the continuation of IK-595 development activities, Ikena has begun to explore a range of available strategic alternatives



"Ikena is in a strong position to create value through multiple avenues. We have been diligent with our capital expenditure, fortifying a cash position that may unlock new strategic opportunities for the company, in addition to the parallel partnership potential of our pipeline," said Jotin Marango, M.D., Ph.D., Ikena's Chief Financial Officer.

About Ikena Oncology

Ikena Oncology® develops differentiated therapies for patients in need that target nodes of cancer growth, spread, and therapeutic resistance. 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.

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 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; expectations with respect to projected cash runway; the anticipated results of our organizational changes; 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; 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, 2024, which is on file with the Securities and Exchange Commission (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.

Ikena Contact:

Rebecca Cohen
rcohen@ikenaoncology.com



Corporate Presentation

Second Quarter 2024

Forward Looking Statement

Any statements in presentation other than statements of historical fact are forward-looking statements. Forward-looking statements include, but are not limited to, statements about future expectations, plans and prospects for Ikena Oncology, Inc. including statements regarding the market and therapeutic potential of IK-595, the size of various patient populations, the expectation that clinical activity will be consistent with preclinical data, the potential partnerships or combinations of IK-595 and other statements containing the words “will,” “would,” “continue,” “expect,” “should,” “anticipate” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of Ikena’s experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, geopolitical factors and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The various factors that could cause Ikena’s actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements, include, but are not limited to, its ability to obtain funding for its operations necessary to complete further development and commercialization of its product candidates, the rate and degree of market acceptance of its product candidates, its reliance on third-parties, including the ability and willingness of its third-party strategic collaborators to continue research and development activities relating to its development candidates and product candidates, and its ability to contract with third-party suppliers and manufacturers and their ability to perform adequately. No assurance can be given that such expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional risks and information about potential impacts of financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect Ikena can be found in Ikena’s filings, including its most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Forward-looking statements in this communication are based on information available to us, as of the date of this communication and, while we believe our assumptions are reasonable, actual results may differ materially. Subject to any obligations under applicable law, we do not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

Ikena is Focused on Differentiated Therapies for RAS and RAF Altered Cancers

Advancing a novel MEK-RAF molecular glue with the potential to transform outcomes in areas of high unmet need



- IK-595 is designed to overcome the limitations of existing MEK and next gen MEK-RAF inhibitors with broad potential for patients with mutations across the RAS field both as a monotherapy and in combination
- IK-595 is designed with a greater therapeutic index and strong binding glue of MEK-RAF complex
- Dose escalation ongoing; **early PK and PD data encouraging toward potential optimized therapeutic window**; recruiting RASm and RAFm patients
- Company ended Q1 2024 with >\$157M in cash with ongoing efforts to maximize shareholder value including potential strategic alternatives

¹ACS and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3457779/>

Significant Unmet Need in RAS and RAF Altered Cancers

Delivering a BIC MEKi could transform the armamentarium of MAPK targeted therapies



✦ **Pancreatic cancer** is diagnosed in **~500,000 patients annually** worldwide, with **~90% harboring KRAS mutations**

Both incidence and mortality have increased over the last 3 decades worldwide
Effective treatment options are limited resulting in **less than 5%** of advanced patients **alive at 5 years** underscoring the **significant unmet need**^{2,4,5}

✦ **Colorectal cancer** is the **third most common cancer**; projected to increase to 3.2 million new cases worldwide by 2040 & **~40-55% harboring KRASm and/or NRASm**¹

RAS/RAF alterations have also been implicated in **acquired resistance to EGFRi in CRC**
As **third leading cause of cancer deaths**, **outcomes in advanced disease are poor** with a **15% survival rate at 5 years**^{1,2}

✦ **BRAF II/III and CRAFm** represent **targeted populations across multiple tumor types** (~1.4% overall with higher frequency in melanoma, NSCLC and CRC) where **IK-595 has a potentially unique MoA advantage** in multiple indications that are **completely unaddressed by existing therapies**³

¹Multi source: Arch Med Sci 2022, Frontiers 2022, Morgan E, et al. Gut 2023;72:338-344, Nature. 2012 Jun 28;486(7404):537-40; ²CA Cancer J Clin. 2020;70(03):145-164; ³Multi source: Exp Biol Med 2021, Cancer Discov. 2017 Aug;7(8):818-831; ⁴Multi source: Clin Med. 2024 Apr 4;13(7):2103, World J Gastroenterol. 2022 Aug 28; 28(32): 4698-4715., A Cancer J Clin. 2021 May;71(3):209-249.

Unique MoA and Differentiated Profile Unlock Efficacy Opportunities Unachievable with Existing Therapies

Preclinical data shows potential for superiority to 1st gen MEKi, Pan-RAFi and MEK-RAF combinations

IK-595 glues MEK & RAF in an inactive complex to prevent CRAF bypass and kinase-independent CRAF function



IK-595 MOA DESIGN FOR SUPERIOR PATHWAY INHIBITION

Stabilizes MEK and all RAF isoforms in an inactive conformation

- Inhibits MEK and ERK1/2 phosphorylation
- Alleviates therapeutic resistance through CRAF-mediated bypass
- Less susceptible to ARAF-mediated resistance

TUNED PK ENABLES BREAKS IN NORMAL TISSUE

PK profile designed to maximize human therapeutic index

- Intermittently high exposures to drive antitumor activity while sparing healthy cells

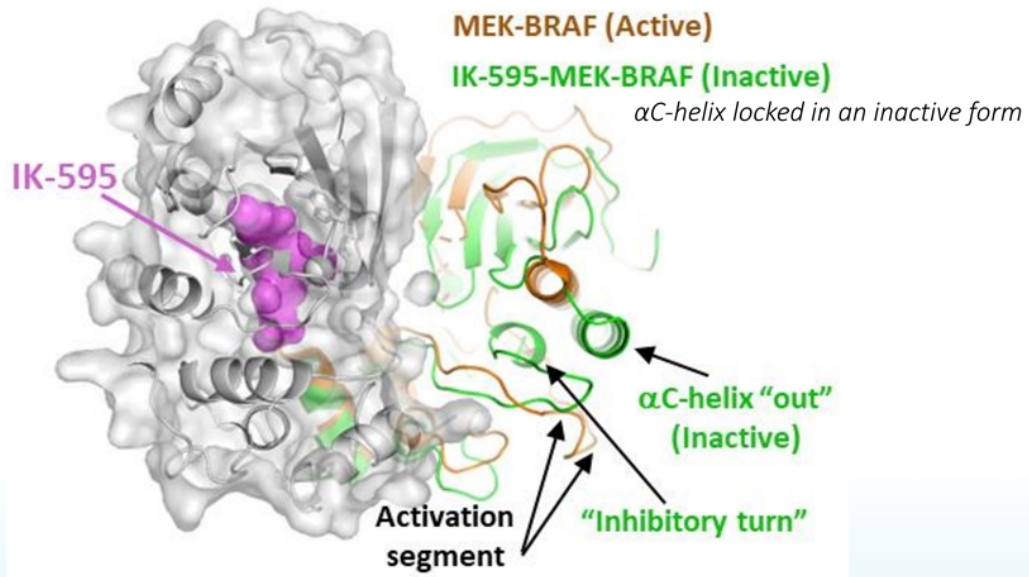
AIMING TO ADDRESS BROAD UNMET CLINICAL NEED

Clinical opportunity in indications unaddressed with current therapies

- NRASm, KRASm, other MAPK-dependent cancers such as BRAFm type II/III or CRAFm
- Combines synergistically with inhibitors to RAS, compensatory pathways and chemotherapies

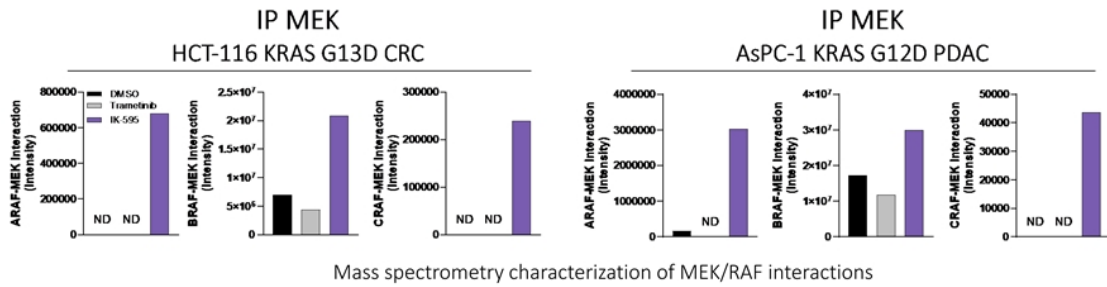
IK-595 Stabilizes MEK-RAF in an Inactive Conformation

IK-595 Co-Crystal Structure with MEK-BRAF Complex

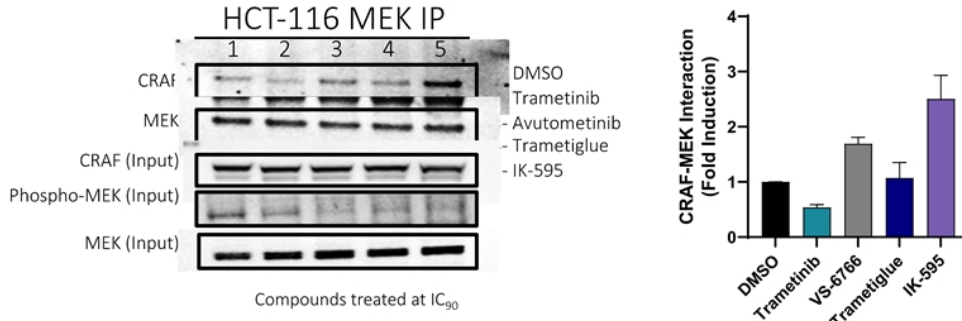


Inactive conformation designed to prevent RAF dimer formation; essential for downstream signaling in KRAS/NRAS tumors

IK-595 Stabilized MEK-CRAF, MEK-BRAF, and MEK-ARAF Complexes in Cells



ND: Not detected



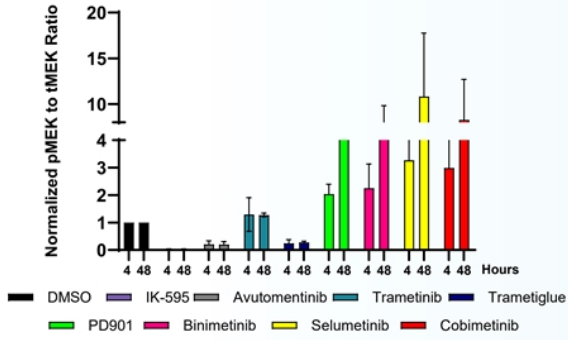
IK-595 also stabilized Class I, II and III BRAF mutant proteins in inactive complex with MEK

IK-595 Demonstrates Robust and Prolonged pMEK and pERK Inhibition

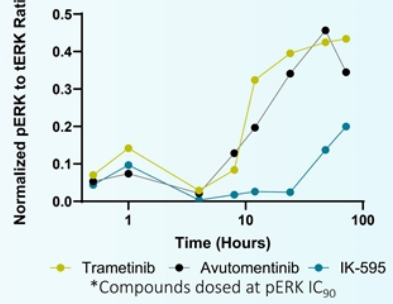
pERK Inhibition is Downstream of MEK and Prolonged Inhibition Demonstrates Lack of Feedback Activation

pMEK Inhibition Indicative of Blocking RAF Activity

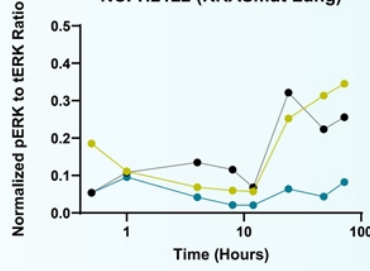
In vitro MEK Phosphorylation (HCT116 cells)



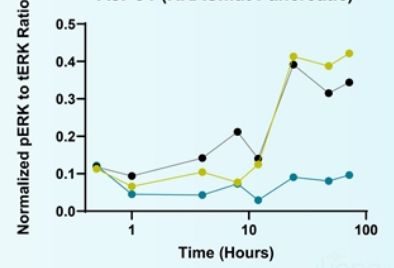
5637 (CRAF amplified Bladder)



NCI-H2122 (KRASmut Lung)

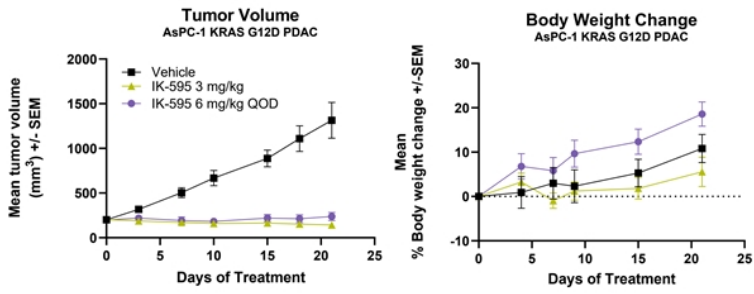


AsPC1 (KRASmut Pancreatic)

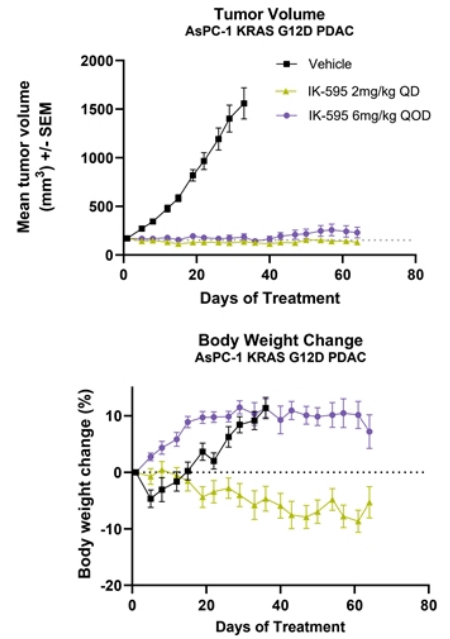


IK-595 Dosed Intermittently Maintained In Vivo Efficacy while Improving Tolerability

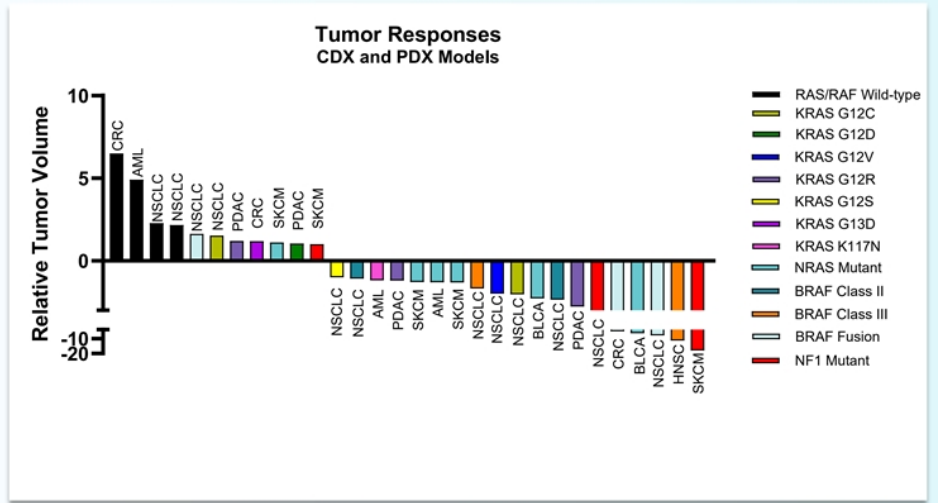
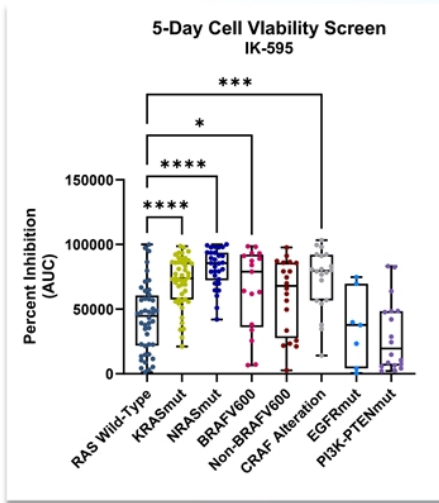
Challenging Model Showing Efficacy and Tolerance at Multiple Doses



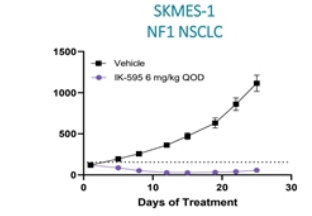
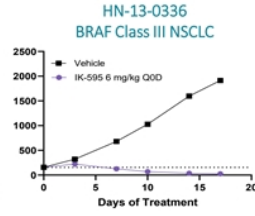
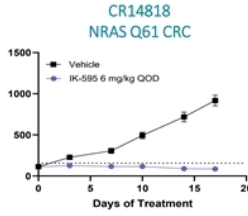
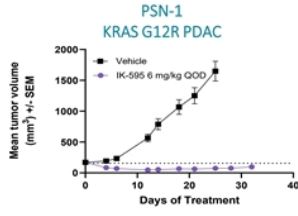
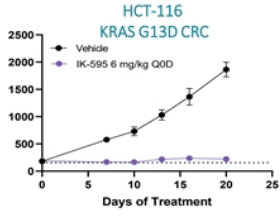
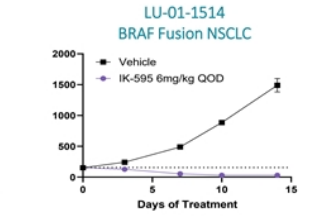
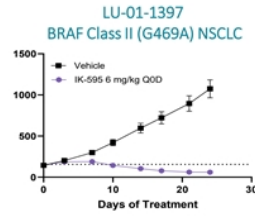
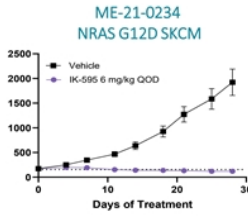
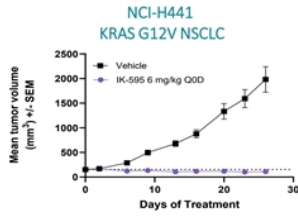
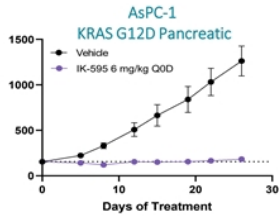
Long-term IK-595 Intermittent Dosing Well Tolerated



IK-595 Demonstrated Antitumor Activity Across Tumor Models Bearing RAS/MAPK Pathway Alterations

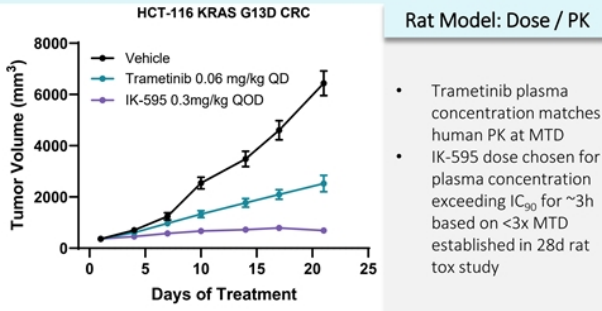


Broad IK-595 Antitumor Activity Across MAPK Pathway Mutant Cancer Models

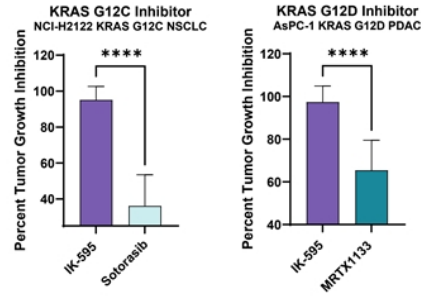


Superior Anti-tumor Activity Compared to other MAPK Pathway Inhibitors

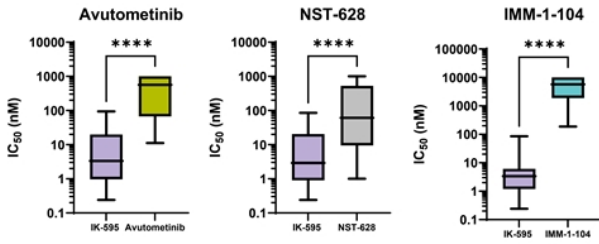
Superior activity vs. 1st Gen MEK inhibitors



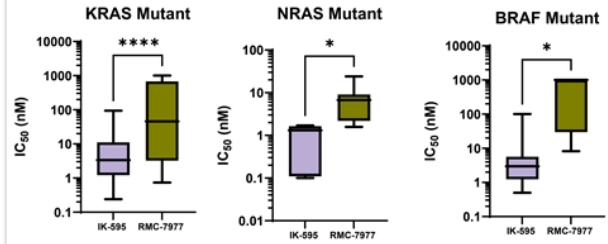
Superior activity vs. mutant-specific RAS inhibitors



Superior activity vs. 2nd Gen MEK inhibitors

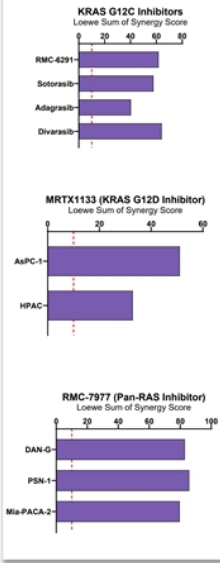


Superior activity vs. pan-RAS inhibitor

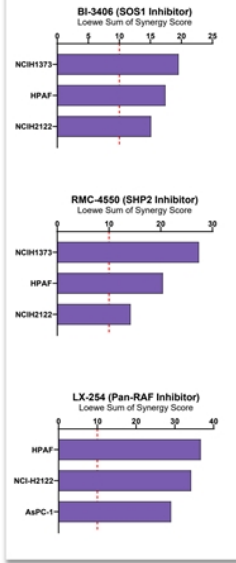


Synergy of IK-595 with Multiple Combo Agents; Broad Expansion Opportunities Beyond Monotherapy

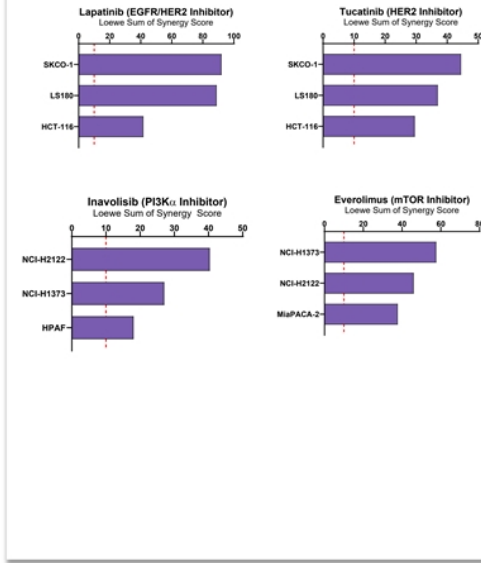
RAS Inhibitors



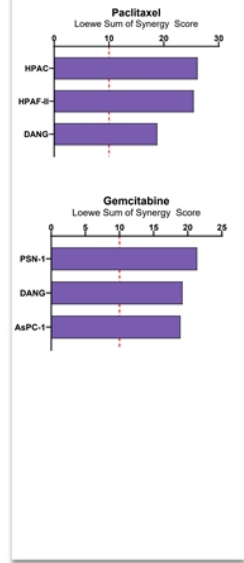
In-Pathway Combinations



Mediators of Resistance



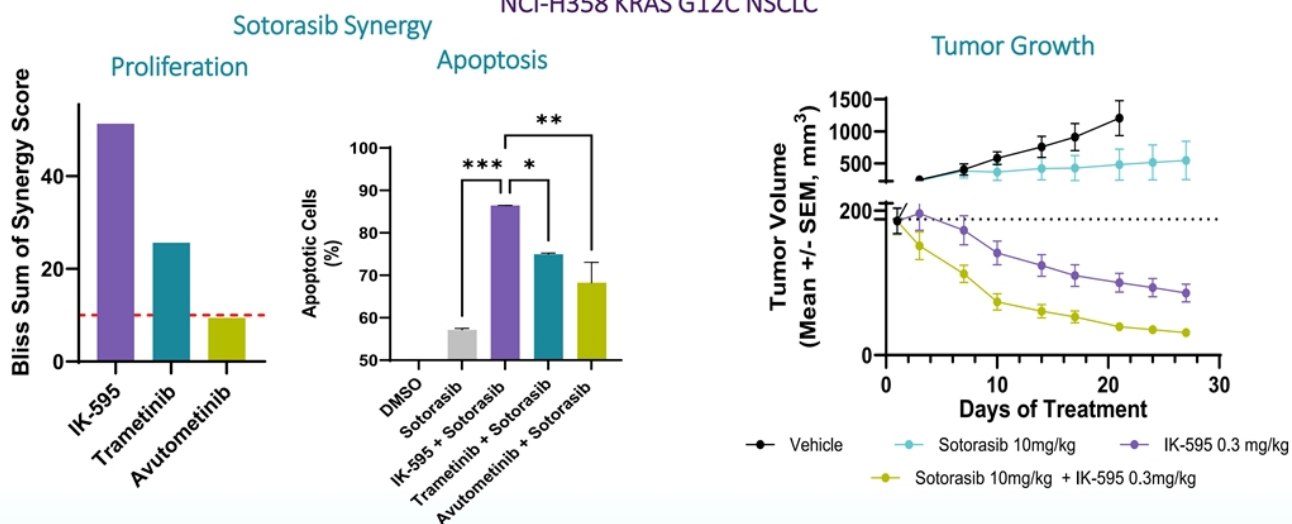
Chemotherapy



IK-595: Potentially Optimal MAPK Combo Partner, Outperformed 1st and 2nd Gen MEKi Preclinically

Opportunity for combination with G12Ci and broader RASi field as it develops

NCI-H358 KRAS G12C NSCLC

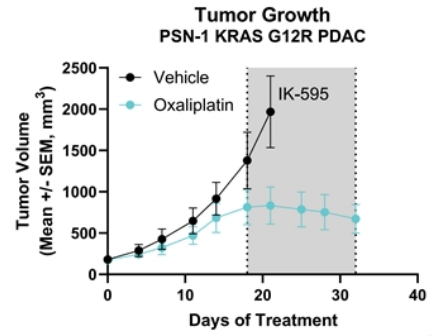
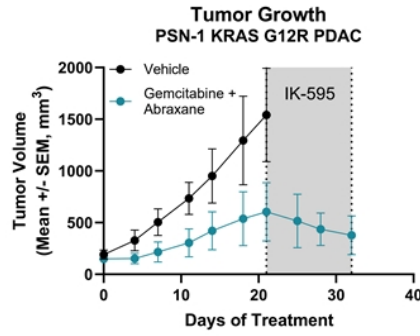
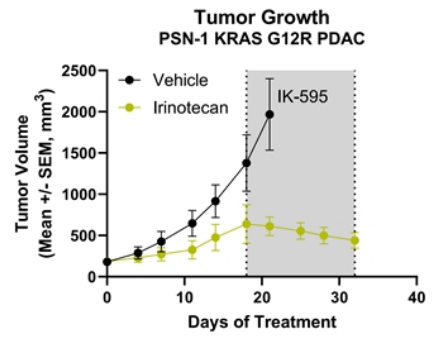
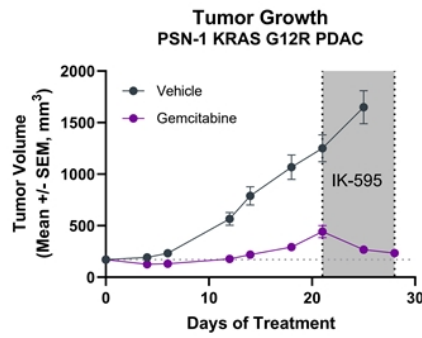


Beneficial antitumor activity also observed when IK-595 was combined with G12C on-state inhibitors, G12D inhibitors and pan-KRAS inhibitors as well as in G12C resistant tumor models

Combo Partner of Choice: IK-595 Added Significant Preclinical Tumor Benefit in Chemo-Resistant PDAC

PSN-1 KRAS G12R PDAC Model

Adding IK-595 after tumor growth increases, in multiple chemo regimens, include gemcitabine, 1st line SOC in PDAC, triggered tumor regression



Clinical Strategy Capitalizes on BIC Profile to Explore Early PoC in MEKi Differentiated Indications

Dose Escalation

Advanced Solid Tumor Pts Harboring Alterations in the RAS-MAPK Pathway

- Starting dose 0.5 mg QoD, currently evaluating 2mg QoD
- Safety and Tolerability, RP2D and/or MTD of IK-595
- Pharmacokinetics
- Pharmacodynamics in blood and tumor
- Antitumor activity per RECIST 1.1
- Flexibility for dose schedule exploration to optimize therapeutic profile
- Option to Backfill dose cohorts with targeted expansion indications



Dose Expansion

Dose expansion guided by dose escalation and potential backfill populations

NRASm, including e.g. CRC, melanoma

KRASm, including e.g. PDAC, CRC, NSCLC

Tumor agnostic, e.g. BRAFm type II/III or CRAFm

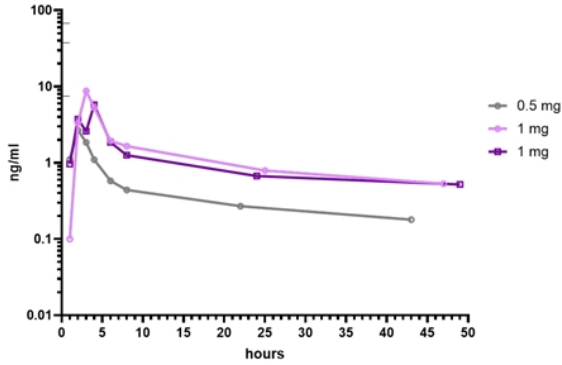
Potential combinations include other targeted therapies in RAS/RAF pathway, mAbs, chemo

Ongoing Enrollment in Phase 1 Dose-Escalation Trial of IK-595 as a Monotherapy and in Combination

Preliminary PK and PD Data Supports Intermittent Dosing and Optimized Therapeutic Index

Robust pathway inhibition observed with recovery in dosing interval

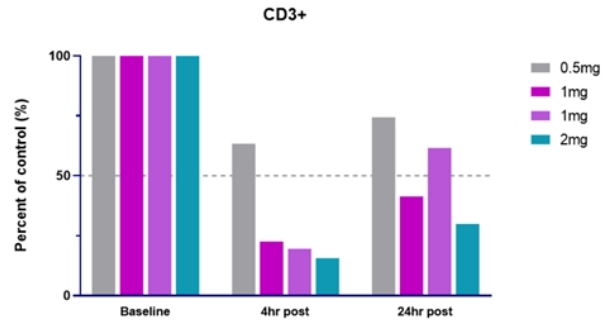
Achieved transient, high plasma concentrations to drive pathway inhibition with recovery before next dose



Data from 2mg cycle 1 day 1 pending

Dose dependent pERK suppression with recovery during dosing interval

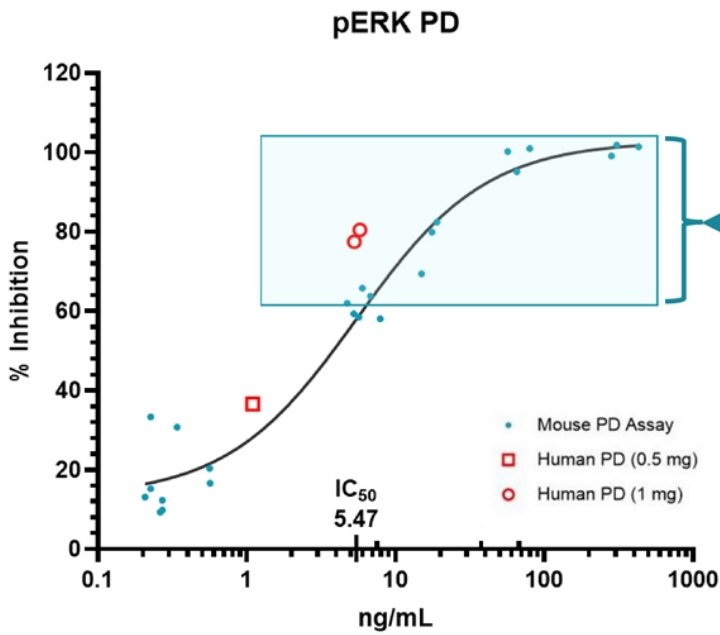
IK-595 at 1mg approaches Emax of approved MEKi¹



Preliminary data from the ongoing Study IK-595-001, data cut 05/23/2024

¹Clin Cancer Res 2010 Mar 1;16(5):1613-23.

Preliminary Human PK/PD Consistent with Translational Data in Mouse Models



- IK-595 demonstrated tumor PD and anti-tumor activity in some mouse xenograft models at doses where blood pERK inhibition is >60% 2-4 Hrs after dosing (shaded box)

← Doses associated with antitumor activity in mouse models

Data suggest that clinical doses ≥ 2 mg could potentially achieve the level of PD associated with antitumor activity in mouse models

Ikena is Aims to Address Key Gap in the Targeted RAS Pathway Treatment Ecosystem

Advancing a novel MEK-RAF molecular glue with the potential to transform outcomes in areas of high unmet need

POTENTIAL BEST IN CLASS MEK/RAFI

- ✓ Developed to deliver an **optimized therapeutic index**
- ✓ Designed to **overcome resistance** to MAPK targeted therapies
- ✓ Potential to rise as **combination partner of choice**

DATA DRIVEN CLINICAL STRATEGIES

- Confirm BIC profile; optimize dose and schedule:
 - PK/PD/Safety/Efficacy in targeted indications
- Monotherapy Testing in RASm, RAFm cancers
- Combinations with potential to broaden indications and move to earlier lines

Efficient Potential Fast to Market Strategies as a Monotherapy

Rapid Initiation of Combination Strategy to Maximize Asset Potential

High Unmet Need and Meaningful Market Opportunities to Drive Potential Value

Ikena ended Q1 2024 with >\$157M in cash

IK-595 is well positioned for potential near-term value inflections



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ONCOLOGY