# 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): March 18, 2025**

# TUHURA BIOSCIENCES, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Nevada** | **001-37823** | **99-0360497** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**10500 University Center Dr., Suite 110**
**Tampa, Florida 33612**

**(Address of Principal Executive Offices, including zip code)**

**Registrant's Telephone Number, Including Area Code: (813) 875-6600**

**N/A**
**(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** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, $0.001 par value per share | HURA | The Nasdaq Capital 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. ☐

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**Item 7.01 Regulation FD Disclosure.**

On March 18, 2025, representatives of TuHURA Biosciences, Inc. (the "Company" or "TuHURA") began making presentations to investors, analysts, and others using the investor presentation attached to this Current Report on Form 8-K as Exhibit 99.1 (the "Investor Presentation"). The Company expects to use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others from time to time.

By filing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report, which is required to be disclosed solely by reason of Regulation FD. The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

*Additional Information about the Proposed Mergers and Where to Find It*

This communication may be deemed to be solicitation material with respect to the proposed transactions between TuHURA and Kineta, Inc. ("Kineta"). In connection with the proposed transactions, TuHURA intends to file relevant materials with the SEC. TuHURA will mail the joint proxy statement/prospectus to the TuHURA stockholders. ***Investors and securityholders of TuHURA and Kineta are urged to read these materials when they become available because they will contain important information about TuHURA, Kineta and the proposed transactions. This communication is not a substitute for the definitive proxy statement/prospectus, when it becomes available, or any other documents that TuHURA may file with the SEC or send to securityholders in connection with the proposed transactions.***

Investors and stockholders will be able to obtain free copies of the documents filed or that will be filed with the SEC by TuHURA, when they become available, through the website maintained by the SEC at www.sec.gov. The documents filed by TuHURA with the SEC may also be obtained free of charge at TuHURA's website at www.tuhurabio.com or upon written request to: TuHURA, 10500 University Drive, Suite 110, Tampa, Florida 33612.

*No Offer or Solicitation*

This Current Report on Form 8-K is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and is not intended to and does not constitute an offer to sell or the solicitation of an offer to buy the securities of TuHURA or Kineta, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to

registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act.

*Participants in the Solicitation*

TuHURA and Kineta and their respective directors and officers and other members of management may, under SEC rules, be deemed to be participants in the solicitation of proxies from stockholders in connection with the potential transaction and other matters that may be set forth in the proxy statement/prospectus. Information about TuHURA's directors and executive officers is set forth in TuHURA's filings with the SEC, including TuHURA's Registration Statement on Form S-4 filed with the SEC on February 7, 2025. Additional information regarding the direct and indirect interests, by security holdings or otherwise, of those persons and other persons who may be deemed participants in the solicitation of proxies in the potential transaction may be obtained by reading the proxy statement/prospectus when it becomes available. You may obtain free copies of these documents as described above under "Additional Information about the Proposed Mergers and Where to Find It ".

*Cautionary Statement Regarding Forward-Looking Statements*

This document contains certain "forward-looking statements" within the meaning of, and subject to the safe harbor created by, Section 27A of the Securities Act, Section 21E of the Exchange Act and the Private Securities Litigation Reform Act of 1995, which are referred to as the safe harbor provisions. Statements included herein are not historical facts are forward-looking statements, including statements about the beliefs and expectations of the management of each of TuHURA and Kineta. In some cases, you can identify these statements by terminology such as "may," "should," "plans," "believe," "will," "anticipate," "estimate," "expect," "project," or "intend," including their opposites or similar phrases or expressions. TuHURA and Kineta caution investors that any forward-looking statements, including statements related to anticipated operating results, business strategies and outlook of TuHURA and Kineta, proposed financing for the transaction, anticipated benefits of the Mergers, the anticipated impact of the Mergers on TuHURA's and Kineta's business and future financial and operating results, the expected amount and timing of synergies from the Mergers, the anticipated closing date for the Mergers and other aspects of Kineta's and TuHURA's operations or operating results, are only predictions and involve known and unknown risks and uncertainties, many of which are beyond TuHURA's and Kineta's control, and could cause actual results to differ materially from those indicated in such forward-looking statements, which speak only as of the date of this Form 8-K. These factors, risks and uncertainties include, but are not limited to: the completion of the Mergers on anticipated terms and timing, anticipated tax treatment and unforeseen liabilities, future capital expenditures, revenues, expenses, earnings, synergies, economic performance, indebtedness, financial condition, losses, pricing trends, future prospects, credit ratings, business and management strategies which may adversely affect each of TuHURA's and Kineta's business, financial condition, operating results and the price of their respective common stocks; the failure to satisfy the conditions to the completion of the Mergers, including the adoption of the Merger Agreement by the stockholders of Kineta and TuHURA's completion of the Concurrent Investment, in a timely manner, or at all, or the failure to satisfy any of the other conditions to the completion of the Mergers, or unexpected delays in satisfying any conditions; uncertainties related to Kineta's cash level and ability to continue as a going concern; the price of TuHURA Common Stock and Kineta Common Stock could change before the completion of the Mergers, including as a result of uncertainty as to the long-term value of the common stock of TuHURA or as a result of broader stock market movements; risks relating to the amount of Kineta's Estimated Net Working Capital Amount at the Closing, including any resulting reduction or adjustments to the Merger Consideration or failure of the condition that Kineta's Estimated Net Working Capital Deficit not exceed $12,000,000 at the Closing; uncertainties as to access to available financing, including the Concurrent Investment, to complete the Mergers upon acceptable terms and on a timely basis or at all; the occurrence of any event, change or other circumstance that could give rise to the termination of the Merger Agreement, including a termination of the Merger Agreement under circumstances that could require Kineta to pay a termination fee to TuHURA; risks that the Mergers do not qualify as a reorganization under the Code; the risk that, if the Mergers or another strategic transaction is not successfully completed, the Kineta board of directors may decide to pursue a dissolution and liquidation of Kineta; the effect of the announcement or pendency of the transaction on Kineta's or TuHURA's business relationships, competition, business, financial condition, and operating results; risks that the Mergers disrupt current plans and operations of Kineta or TuHURA and the ability of Kineta or TuHURA to retain and hire key personnel; risks related to diverting either management team's attention from ongoing business operations of Kineta or TuHURA; the outcome of any legal proceedings that may be instituted against Kineta or TuHURA related to the Merger Agreement or the transaction; the ability of TuHURA to successfully integrate Kineta's business or fully realize the anticipated synergies or other benefits expected from the Mergers; the ability of TuHURA to implement its plans, forecasts,

expected financial performance and other expectations with respect to Kineta's business or the combined business after the completion of the Mergers and realize additional opportunities, develop customer relationships, additional products and Kineta's existing business; risks associated with third party contracts containing consent and/or other provisions that may be triggered by the Mergers; the potentially significant amount of any costs, fees, expenses, impairments or charges related to the Mergers; the risk of no amounts being payable under the Disposed Asset Payment Right; the potential dilution of TuHURA and Kineta stockholders' ownership percentage of TuHURA after the Mergers as compared to their ownership percentage of TuHURA and Kineta, as applicable, prior to the Mergers; TuHURA and Kineta directors and executive officers having interests in the Mergers that are different from, or in addition to, the interests of TuHURA and Kineta stockholders generally; macroeconomic conditions and geopolitical uncertainty in the global economy; uncertainty in the growth of the biopharmaceutical sector; the highly competitive industries TuHURA and Kineta operate in; actions by the U.S. or foreign governments, such as the imposition of additional export restrictions or tariffs; legislative, regulatory and economic developments affecting Kineta's and TuHURA's businesses; the evolving legal, regulatory and tax regimes under which Kineta and TuHURA operate; restrictions during the pendency of the Mergers that may impact Kineta's or TuHURA's ability to pursue certain business opportunities or strategic transactions, and unpredictability and severity of catastrophic events, including, but not limited to, acts of terrorism or outbreak of war or hostilities, as well as Kineta's and TuHURA's response to any of the aforementioned factors. The foregoing list of risks, uncertainties and factors is not exhaustive. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements.

You should carefully consider the foregoing factors and the other risks and uncertainties that affect the businesses of TuHURA and Kineta described in the "Risk Factors" section of their respective Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed by either of them from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. All forward-looking statements by their nature address matters that involve risks and uncertainties, many of which are beyond TuHURA's and Kineta's control, and are not guarantees of future results. Readers are cautioned not to put undue reliance on forward-looking statements, and TuHURA and Kineta assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law. Neither TuHURA nor Kineta gives any assurance that either TuHURA or Kineta will achieve its expectations.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

**Exhibit**

**No. Document**

99.1 Investor Presentation dated March 2025

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

**SIGNATURES**

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

**TUHURA BIOSCIENCES, INC.**

Date: March 18, 2025

By: */s/* Dan Dearborn
Name: Dan Dearborn
Title: Chief Financial Officer

Filed by TuHURA Biosciences, Inc.
Pursuant to Rule 425 under the Securities Act of 1933
and deemed filed pursuant to Rule 14a-12
under the Securities Act of 1934

Filer: TuHURA Biosciences, Inc.
Commission File No.: 001-37823

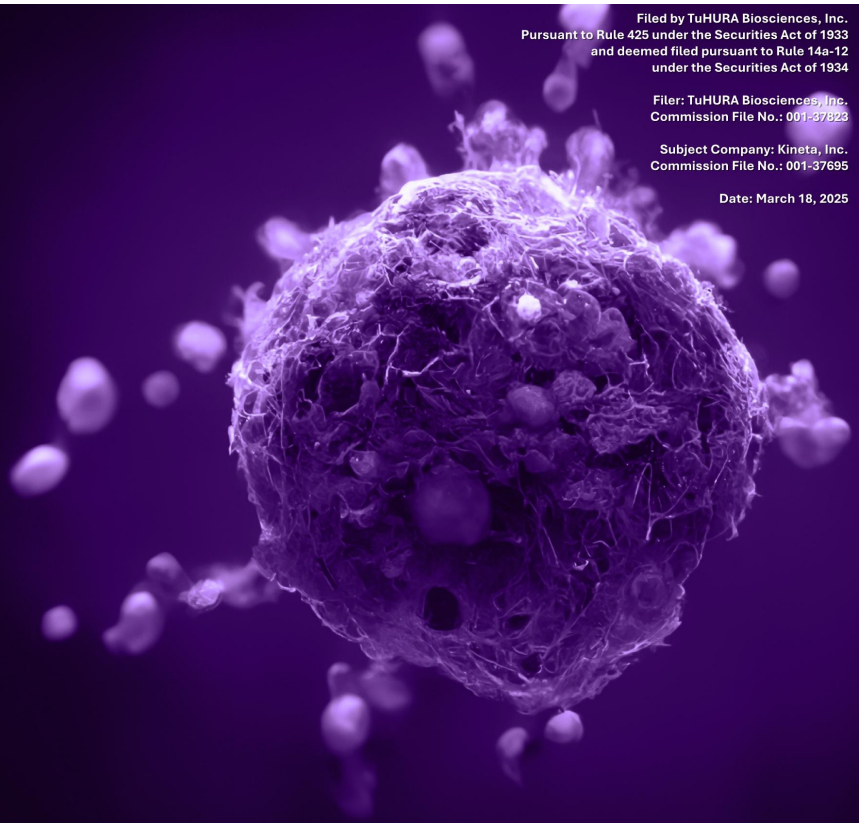
Subject Company: Kineta, Inc.
Commission File No.: 001-37695

Date: March 18, 2025

TuHURA biosciences

# Overcoming Resistance to Cancer Immunotherapy

**Presentation | March 2025**



tuhurabio.com

# Forward-Looking Statements

This presentation includes “forward-looking statements” under the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and TuHURA's actual results may differ from its expectations, estimates and projections expressed in its forward-looking statements, and consequently you should not rely on these forward-looking statements as predictions of future events. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “continue,” and similar expressions are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, statements about TuHURA's IFx-Hu2.0 product candidate, its IFx-Hu3.0 preclinical program, its tumor microenvironment modulators development program, its potential acquisition by merger of Kineta Inc. and the statements about Kineta's VISTA-101 development program, and any developments or results in connection therewith and the anticipated regulatory pathway and timing of those development programs, studies and trials. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results, including the risks set forth in the “Risk Factors” sections of TuHURA's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q , and other documents filed by TuHURA from time wo time with the Securities and Exchange Commission. TuHURA does not undertake or accept any obligation or undertaking to update or revise any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

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# Investment Summary

**Innate Immune Agonists**

✓ **Single Phase 3 registration directed Accelerated Approval trial for IFx-2.0***

- Demonstrated durable CRs and PRs in patients progressing on CPI in Phase 2 trial
- FDA Project Front Runner initiative encouraged trial in first line setting
- SPA Agreement with FDA on novel trial design could remove requirement for post approval confirmatory trial, potentially converting accelerated approval to full approval
- Top-line data anticipated 2H 2026

**Tumor Microenvironment Modulators**

✓ **Building a de-risked late-stage product pipeline**

- Definitive agreement to acquire by merger Kineta's VISTA inhibiting mAb in clinical partnership with Merck
- If completed, Kineta transaction adds Phase 2 stage candidate to development pipeline in NMP1 mutated AML
- First-in-class, non-tumor targeting, bi-specific immune modulating ADCs/APCs

**Business Highlights**

✓ **Clinical, corporate and regulatory milestones with 4 key data readouts expected over the next 24 months**

TuHURA biosciences

* Trial currently subject to partial clinical hold relating to completion of certain CMC requirements for initiation of Phase 3 registration trial
MCC = Merkel cell carcinoma

# 2024 Highlights

- ✓ Successful SPA agreement with FDA
  - Single Phase 3 Accelerated Approval Trial[1]
  - Key 2[0] endpoint (PFS) may satisfy post approval confirmatory trial requirement
- ✓ Acquired Phase 2 ready VISTA inhibitor in clinical partnership with Merck
- ✓ Advanced first-in-class bi-specific immune modulating ADCs/APCs patent estate
- ✓ NASDAQ (HURA) listing via successful reverse merger with Kintara
- ✓ Raised $31mm to fund operations through 2025

# Looking Ahead 2025

**Q2:** Planned initiation of IFx-2.0 Phase 3 trial

**Q2:** IFx-2.0 IR "basket" trial

**Q2:** Target for closing VISTA acquisition

**Q3:** MDSC, M2 macrophage Delta Opioid Receptor validated assay development

Bi-functional ADC (anti-DOR-VISTA)

**Q4:** VISTA inhibitor Phase 2 trial[2]

NPM1 *mut*AML

Society presentations

AACR – ASCO –- ASH

TuHURA biosciences

1. Trial currently subject to partial clinical hold relating to completion of certain CMC requirements for initiation of Phase 3 registration trial
2. Subject to successful acquisition of VISTA asset

MCC = Merkel cell carcinoma

# Diversified Immuno-Oncology Pipeline

| Program | Drug Candidate | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 | Highlight |
|---|---|---|---|---|---|---|---|
| Innate Immune Agonists | IFx-2.0 Tumor-targeted pDNA | **1st Line Merkel Cell Cancer** Keytruda® + IFx-2.0 or placebo | | | | | Phase 3 registration study initiation expected in 1H 2025[2] |
| | | Primary Checkpoint Inhibitor Resistant **Metastatic Cancer "Basket" Trial** | | | | | Phase 2a/b study initiation expected in 1H 2025 |
| | IFx-3.0 Tumor-targeted mRNA | **Diffuse Large B-Cell Lymphoma (DLBCL)** | | | | | Expect to initiate IND-enabling studies in 2H 2026 |
| TME Modulators Negative Immune Regulators | VISTA inhibiting mAb[1] | **NPM1 Mutated Acute Myeloid Leukemia (AML)** | | | | | Expect to initiate Phase 2a/b trial in NPM1 mutated AML in 2H 2025 (contingent on completion of Kineta merger) |
| TME Modulators MDSC Inhibitors | Bi-Specific ADCs and PACs | **Myelodysplasia Acute Myeloid Leukemia** | | | | | ADC/APC *in vivo* POC studies expected in 2H 2025 |

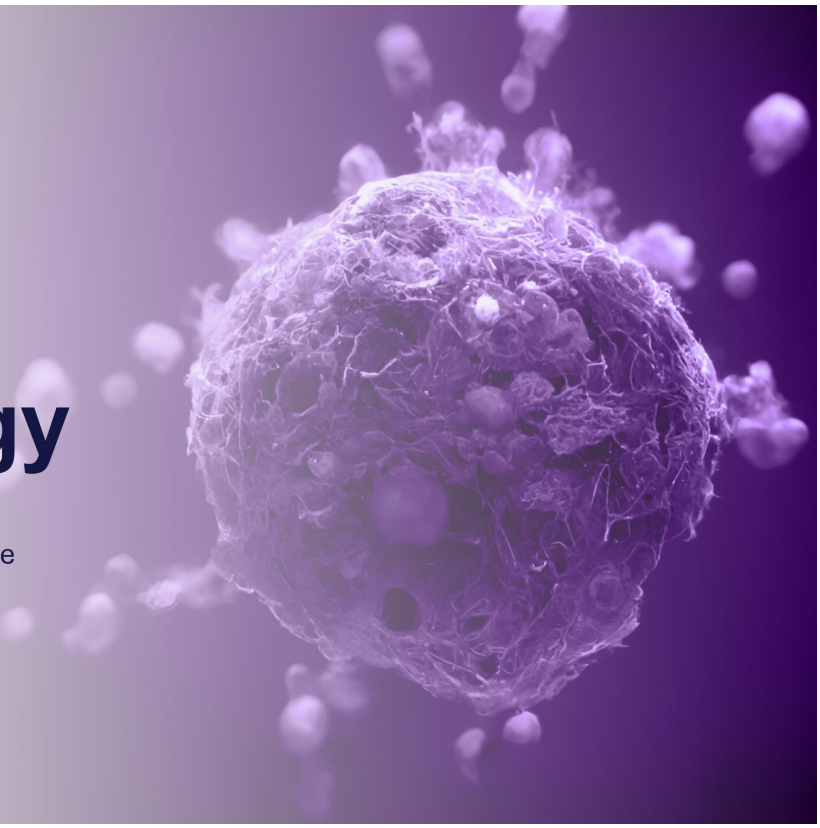
1) Strategic acquisition currently in progress following a signed definitive agreement.
2) Trial currently subject to partial clinical hold expected to be lifted prior to initiation.

TuHURA biosciences

# IFx Technology

## Innate Immune Agonists

Designed to Overcome Primary Resistance to Checkpoint Inhibitors



# IFx-2.0: Mechanism of Action

Making a Tumor Look Like a Bacterium

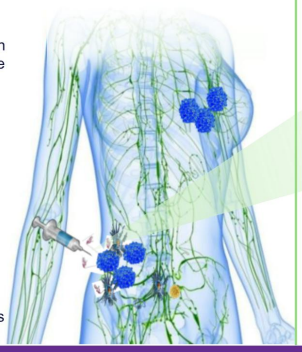
## Initiation of an Innate Immune Response

1

Intra-tumoral injection of pDNA results in expression bacterial protein on surface of tumor – making tumor look like a bacterium

2

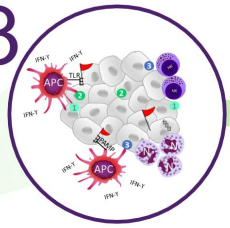
Molecular patterns on bacterial protein conserved through evolution, recognized by pattern recognition receptors (TLR2) on APCs



## Activation of Tumor Specific T Cells

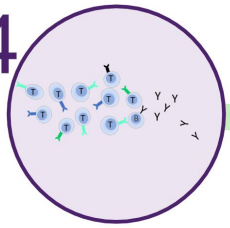
**Allows CPI to work where they previously failed**

3



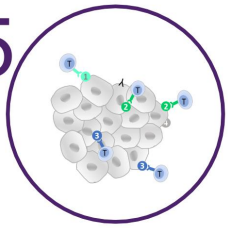

APCs 'ingest" intact tumor cell, package and present all tumor neoantigens to B and T cells leading to activation of tumor specific B and T cells (1$^{o}$ epitope spreading)

4



**Tumor-reactive T and B cell activation, amplification, trafficking and antibody production (adaptive response)**

5



Tumor-specific T cell killing and release of "new/different" tumor antigens (2$^{o}$ epitope spreading)

***Presenting full complement of neoantigens from intact tumor cell*** *provides optimal neoantigen presentation and inter-antigenic epitope spreading more effectively than Oncolytic Viral or Individual Neoantigen Therapy approaches.*



TuHURA biosciences

# Advanced Metastatic Merkel Cell Carcinoma

## Increasing Keytruda's Response Rate is an Attractive Commercial Opportunity

- Keytruda is Standard of Care for 1st line therapy for advanced or metastatic Merkel cell
- Response rates are high (~50%) and long lasting
- However, for the 50% of patients who don't respond there are no approved or alternative therapies
- IFx-2.0 may allow more patients to respond to Keytruda and establish a New Standard of Care for 1st line therapy for MCC


**Complete Response (CR)** | **Partial Response (PR)** | **NO RESPONSE (progressive disease)**

**Probability of disease progression at two years is 26%, 57% and 100% for those with CR, PR and SD, respectively**

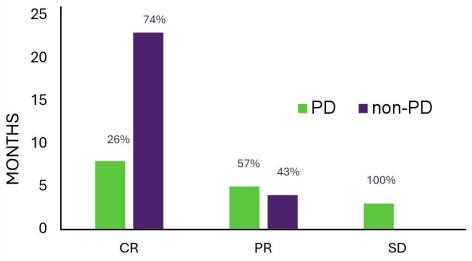



**Figure 1.** Rate of PD based on best ICI response

Sources
N Engl J Med 2016; 374:2542-2552 DOI: 10.1056/NEJMoa1603702
*DelveInsight Merkel Cell Carcinoma (MCC) -- Market Insight, Epidemiology, and Market Forecast – 2034

# Phase 1b Study in Advanced Skin Cancer
*(Merkel Cell and Cutaneous Squamous Cell Carcinoma)*

**Phase 1b**

- Advanced MCC (6) Squamous Cell (3) patients
- Three dosing cohorts:
- IFx-2.0 weekly for one, two or three weeks
- Up to 3 accessible lesions injected
- N=9

**Objectives (on/off protocol)**

- Assess safety of 3 dosing schedules for IFx-2.0
- Determine optimal dose / schedule for maximizing immune response
- Explore tumor response to rechallenge with checkpoint inhibitor post IFx-2.0

**Expanded Trial**

- IFx-2.0 weekly x 3
- CPI naive patients who progressed on 1st line Rx with anti-PD-(L)-1
- Post protocol anti-PD-(L)-1 rechallenge
- N=11 MCC*
- 7/11 pts had no subsequent Rx between 1st line CPI and IFx-2.0

**23 pts enrolled**
**21 safety 19 response**

| | |
|---|---|
| Enrolled | 23 |
| Safety evaluable | 21 |
| Response evaluable | 19 |

**SAFETY: TRAEs**

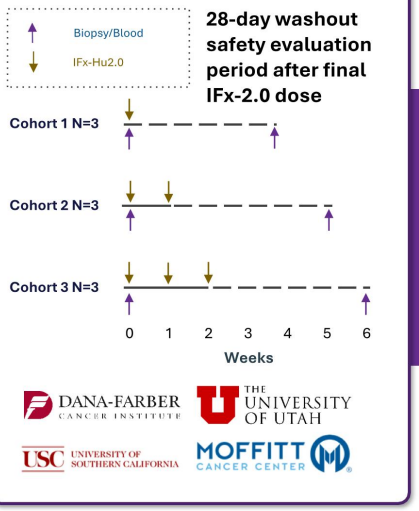
| | |
|---|---|
| Grade 1 | 8(35%) |
| Grade 3 | 1(4%) |

**POST CPI RECHALLENGE**

| | |
|---|---|
| MERKEL (5) | CR -2 |
| | PR -2 |
| | PD -1 |
| MERKEL (2) | PR -1 |
| | PD-1 |

**MEDIAN DOR> 21 months**

**Dose & Schedule Design**



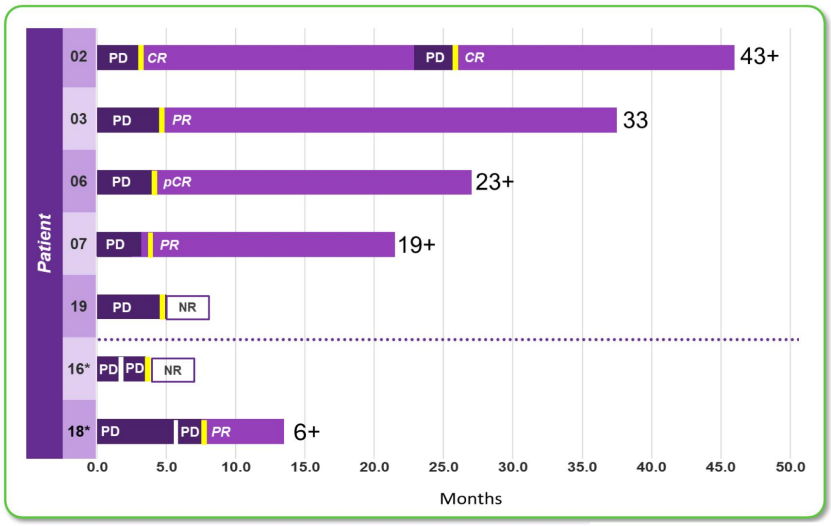

DANA-FARBER CANCER INSTITUTE · THE UNIVERSITY OF UTAH · USC UNIVERSITY OF SOUTHERN CALIFORNIA · MOFFITT CANCER CENTER

TuHURA biosciences

ASCO 2024. Abstract #9592: Phase 1b trial of IFx-Hu2.0, a novel in situ cancer vaccine, in checkpoint inhibitor-resistant Merkel cell carcinoma and cutaneous squamous cell carcinoma

# IFx-2.0 MCC Phase 1b Results Suggest Encouraging Efficacy with Durable Responses

| Phase 1b Dose/Schedule trial | |
|---|---|
| | N (%) |
| Total | 7 |
| CR | 2 (29%) |
| PR | 3 (43%) |
| ORR | 5 (71%) |
| DOR (median) | 21 months+ |
| **SAFETY (n=21)** | |
| Grade 1 | 8 (38%) |
| Grade 3 | 1(5%) |




## Phase 1b Results:

Merkel cell carcinoma n=7

**7 patients** (primary resistance shown)

- **5 progressed** on first line CPI single agent (anti-PD(L) -1) therapy
- **2 progressed** after multiple CPI (anti-PD(L) -1, anti-CTLA-4) therapies*
- No subsequent therapy before IFx-2.0
- Rechallenge with single CPI agent (anti-PD(L)-1 therapy after IFx-2.0

KEY

- Fx-2.0 Administration
- Response to CPI Pre IFx-2.0
- Response to CPI Post IFx-2.0
- NR: No Response

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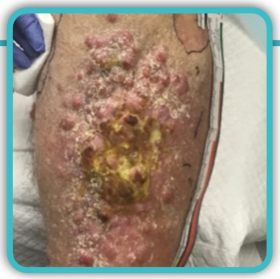
# Overcomes $1^0$ Resistance
# Checkpoint Inhibitors in Merkel Cell Carcinoma

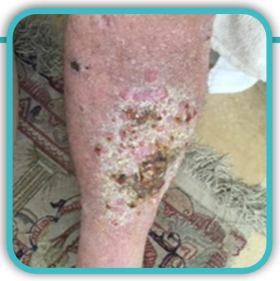
IFx-2.0 Weekly x3 – Followed by Keytruda® (pembrolizumab)

**Progression**

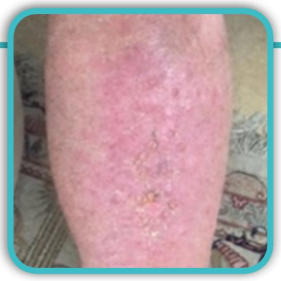
Three months on avelumab, a checkpoint inhibitor



IFx-2.0 Weekly x3
Injected Lesion Not Shown



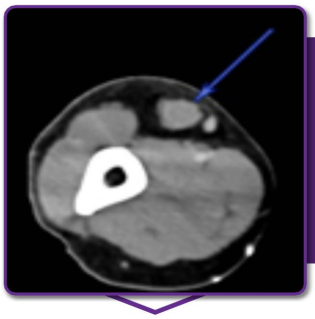
Checkpoint Inhibitor
Keytruda® Rechallenge
Following IFx-2.0



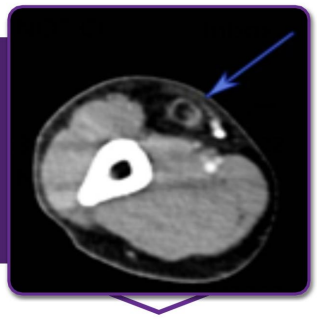
Partial Response (PR)
33 Months

# IFx-2.0 MCC Phase 1b trial

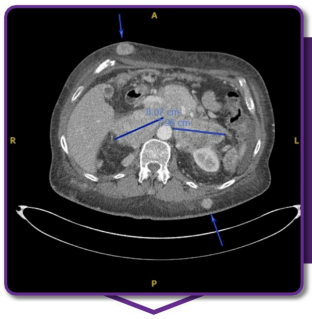
## Overcomes $1^0$ Resistance to Anti-PD-(L)1 Therapy (pembrolizumab or avelumab) in MCC



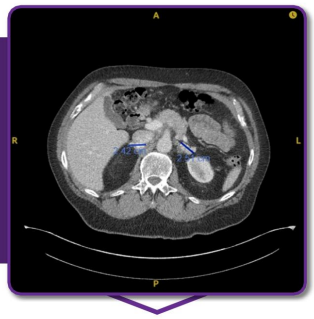
Progressed through 3 months of Keytruda® (pembrolizumab). Large sub-dermal metastatic deposit IFx-2.0 weekly x2 injected into dermal lesions (blue arrows)



Post IFx-2.0 Keytruda® (pembrolizumab) rechallenge. Cavitation of lesion radiographically a PR when excised demonstrated necrotic tissue, no tumor; re-classified as pathologic CR. Response ongoing 23+ months




Progressed through 2 months of Keytruda®. Large bulky abdominal masses (blue) IFx-2.0 weekly x2 injected into dermal lesions (blue arrows)




Post IFx-2.0 rechallenged with checkpoint inhibitor, Bavencio ® (avelumab). Complete disappearance of subcutaneous nodules and ~80% reduction (Partial Response) in abdominal masses. Responses are ongoing 19+ months

# Single Phase 3 Accelerated Approval Trial

## Designed with OCE[1] - Project Front Runner

**1:1 Randomization, Placebo, Injection Controlled Trial[2]**
**1st line CPI naïve, advanced/metastatic MCC**

| Enrolling ~118 patients | IFx-2.0 weekly x 3 + pembrolizumab versus pembrolizumab + placebo | 20-25 U.S. clinical centers |
|---|---|---|

- **SPA Agreement with FDA**
  - ORR allows for potential accelerated approval
  - No requirement for post-marketing trial
  - PFS converts accelerated to full approval
  - Would satisfy requirement for confirmatory trial

**Primary Endpoint**

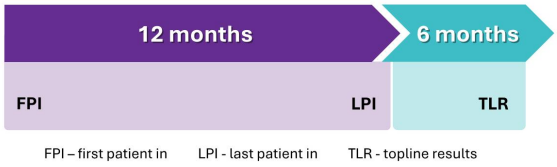
**Overall Response Rate (ORR)**

**Key Secondary Endpoint**

**Progression Free Survival (PFS)**

*(Stepwise hierarchal design preserves alpha)*

**Study Timeline**



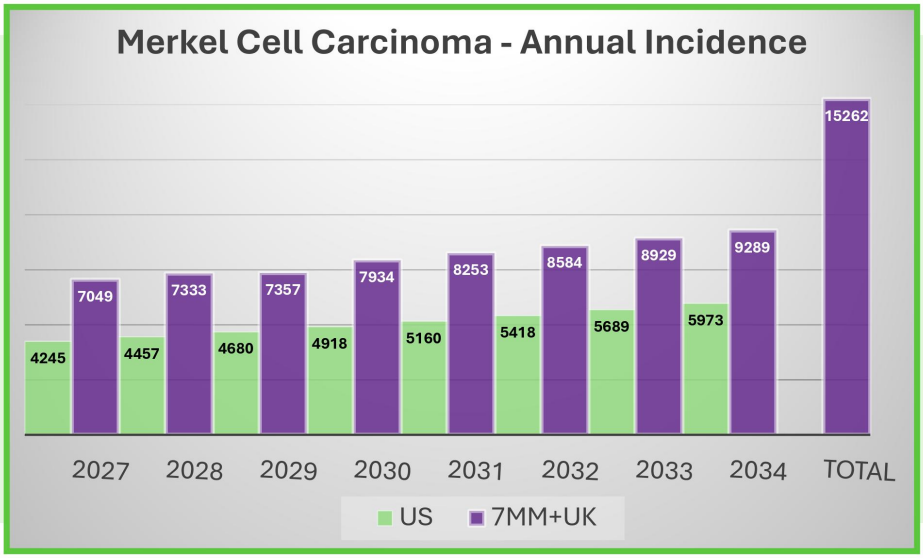

1) Oncology Center of Excellence
2) Trial currently subject to partial clinical hold relating to completion of certain CMC requirements for initiation of Phase 3 registration trial

# Potential Commercial Opportunity – Keytruda® + IFx-2.0

## Assumptions

- ***2034 Peak Market Size (patients)***
  - *Total - 15,262*
  - US – 5,973
  - 7MM+UK – 9,289
- ***US product launch 2027, EU 2028***
- ***Adoption rate ( years 1-3)***
  - *50% to 70% peak penetration*
  - *$150,000 per patient*
  - *COGS 10%*

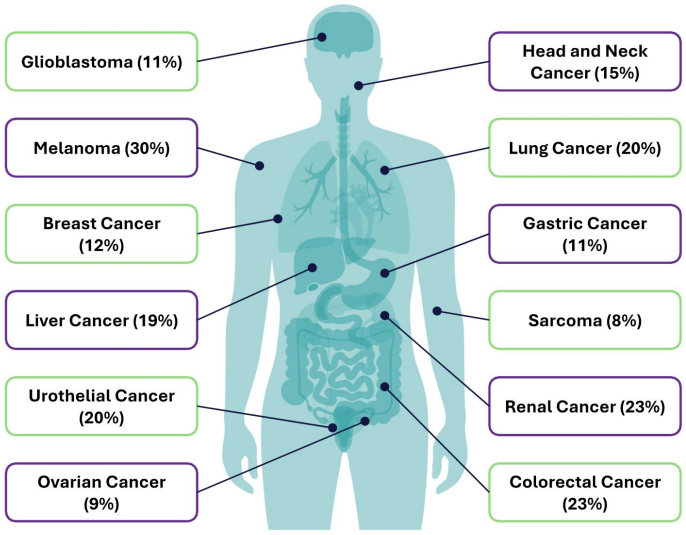
***Peak Sales US only - $627mm***




*Source – Delveinsights Merkel Cell carcinoma, Market Insights, Epidemiology, and Market Forecast – 2034, December 2024,
**Hypothetical Company illustrative proforma model based on assumptions consistent with potential adoption rates for standard of care 1st line therapies and comparable Cost per therapy .

# Attractive Commercial Opportunity: Overcoming Resistance to CPIs

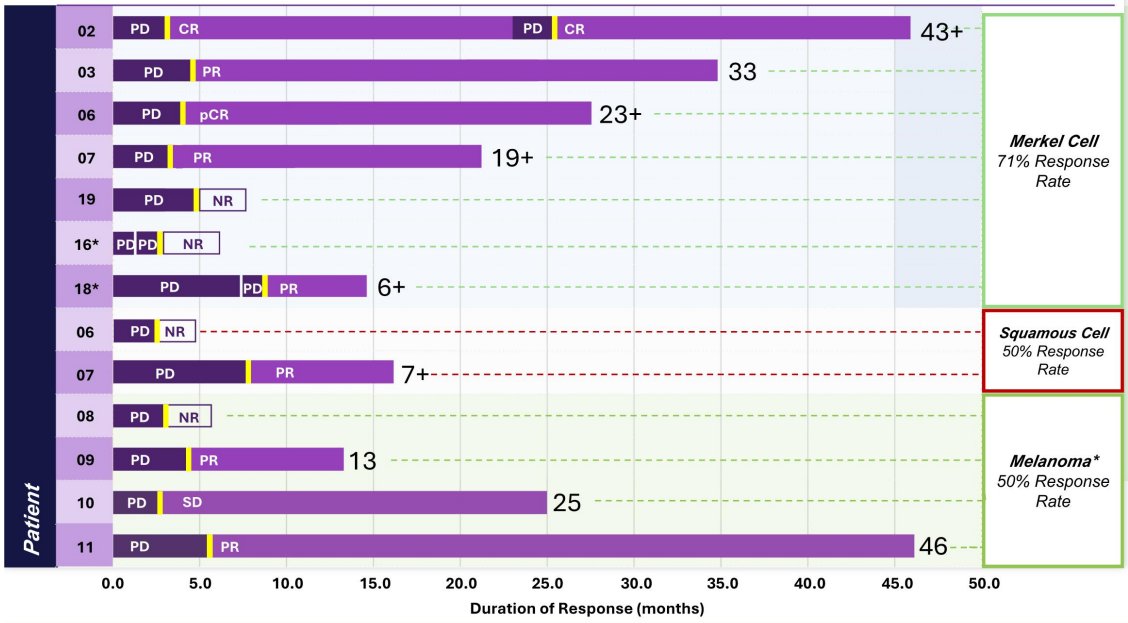
**On average only 20% of patients respond to CPIs**




- **Biology of $1^0$ resistance is common across tumor types (histology agnostic)**
  - Low neoantigen load, low mutational burden
  - **Lack of activated tumor specific T cells**
- **IFx-2.0 innate immune agonist**
  - "Activates" tumor specific T cells which can be checkpoint released
  - Overcomes $1^0$ CPI resistance
- **IFx-2.0 "basket trial" targeting tumors with known resistance to CPIs**
  - Results in Phase 1b Merkel cell study applicable to other tumor types


Sources
1. Zhao B, et al. Ther Ady Med Oncol. 2020;12:1-22;
2. 2. Sun JY, et al. Biomark Res. 2020;8:35; 3. Zhang T, et al. Oncotarget. 2016:7(45):73068-73079.

# IFx-2.0 Demonstrated Ability to Overcome CPI Resistance Across Multiple Tumor Types




## KEY

Response to CPI PRE IFx-Hu2.0

Response POST IFx-Hu2.0 + CPI rechallenge

NR No Response

CR = Complete Response

pCR = Partial Complete Response

PD = Progressive Disease

PR = Partial Response

SD = Stable Disease

## MELANOMA TRIAL OVERVIEW

**Phase 1***: (N=7) Advanced Melanoma, failing chemotherapy, BRAF/MEK inhibitor, 4 patients received and failed CPI

*Mol Cancer Ther 2024;23:1139–43

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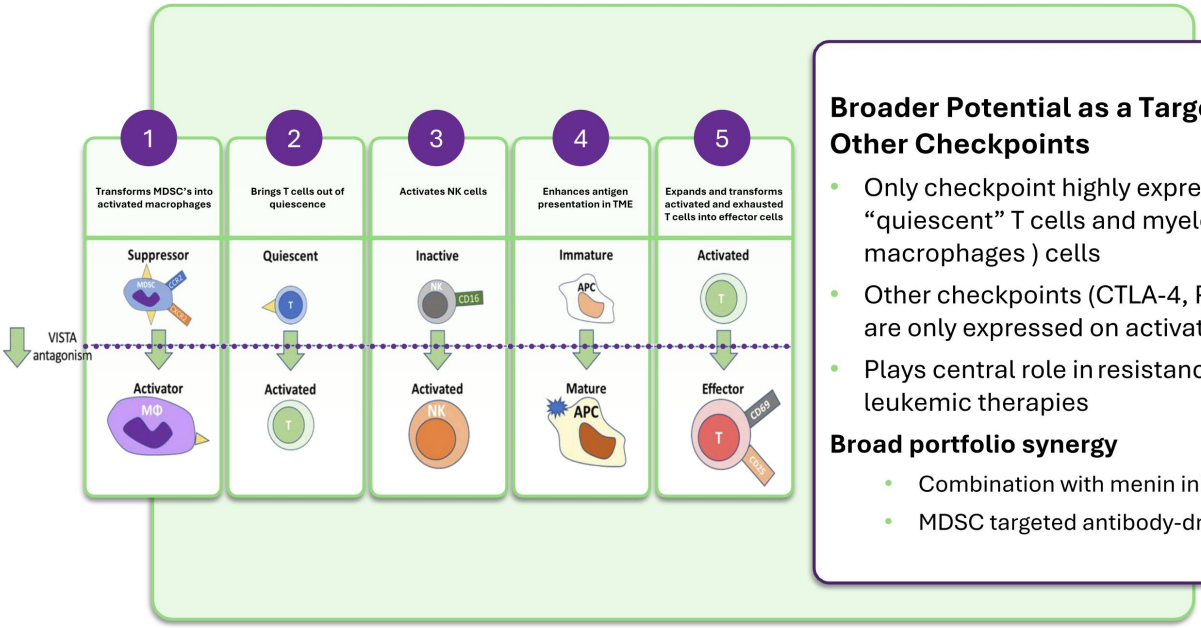
# Tumor Microenvironment Modulators

## Novel Targets for Intervention

- Negative Immune Regulators (VISTA)
- MDSCs and M2 macrophages (DOR inhibitors*)

*DOR – Delta Opioid Receptor

# Targeting VISTA to Overcome Resistance to Immunotherapy




**Broader Potential as a Target Than Other Checkpoints**

- Only checkpoint highly expressed on "quiescent" T cells and myeloid (MDSC, M2 macrophages ) cells
- Other checkpoints (CTLA-4, PD-(L)1, LAG3) are only expressed on activated T Cells
- Plays central role in resistance to anti-leukemic therapies

**Broad portfolio synergy**

- Combination with menin inhibitors in AML
- MDSC targeted antibody-drug conjugates

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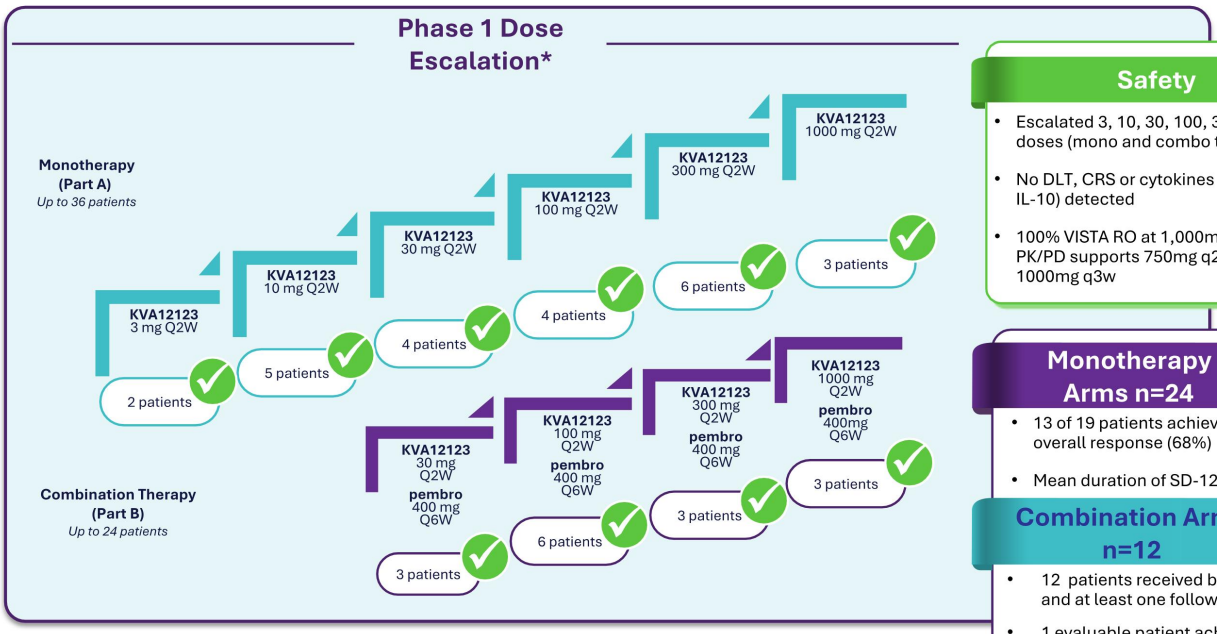
* Formerly KVA12123

# VISTA-101 Phase 1b Clinical Trial




## Safety

- Escalated 3, 10, 30, 100, 300, 1000 mg doses (mono and combo therapy)
- No DLT, CRS or cytokines (IL-6, TNFα & IL-10) detected
- 100% VISTA RO at 1,000mg dose PK/PD supports 750mg q2w or 1000mg q3w

## Monotherapy Arms n=24

- 13 of 19 patients achieved SD as best overall response (68%)
- Mean duration of SD-12 weeks

## Combination Arms n=12

- 12 patients received both baseline and at least one follow up scan
- 1 evaluable patient achieved a **PR,** 1 patient achieved SD

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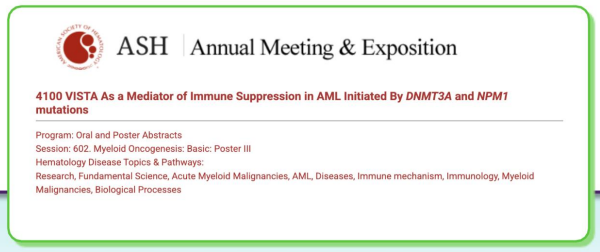
*As of 11-21-24

**Modified BOIN Design with Accelerated Titration**

# VISTA Phase 2 Trial in NMP1 *mutated* r/r AML

## RATIONAL PHASE 2 *mut*NPM1 AML – MENIN +/- VISTA INHIBITING ANTIBODY

- *VSIR* overexpression (encoding VISTA) associated with *mut*NPM1 and VISTA overexpression on AML blasts
- *mut*NPM1 interact with Menin to drive downstream gene expression linked to leukemogenesis
- Menin inhibitors can salvage 25% of *patients with mutNPM1 AML who relapse after 1st line Rx*
- VISTA blockade in combination with Menin inhibitors may represents a new therapeutic strategy for AML patients with relapsed *mut*NPM1 AML.


ASH Annual Meeting & Exposition

**4100 VISTA As a Mediator of Immune Suppression in AML Initiated By *DNMT3A* and *NPM1* mutations**

Program: Oral and Poster Abstracts
Session: 602. Myeloid Oncogenesis: Basic: Poster III
Hematology Disease Topics & Pathways:
Research, Fundamental Science, Acute Myeloid Malignancies, AML, Diseases, Immune mechanism, Immunology, Myeloid Malignancies, Biological Processes

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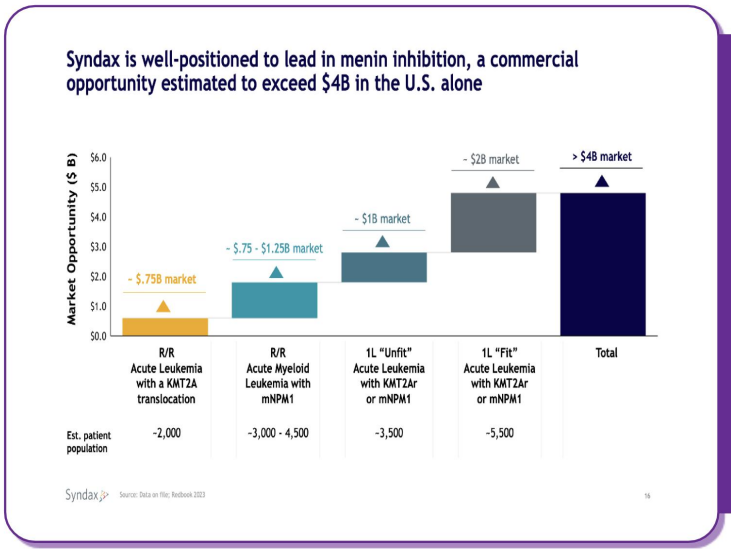
# VISTA : Potential Accelerated Approval Pathway in NPM1 *mut*AML




- NPM1,most common gene mutation in leukemia (AML), produces a protein, menin, which "drives" leukemia
- NPM1 also "drives" VISTA expression on AML cells which leads to evasion of immune attack
- Menin inhibitors are standard of care inr/r NPM1 *mut* AML.
- VISTA + menin inhibitor vs menin inhibitor alone
  - Potential to increase response rate, reduce relapse in AML
- Phase 2 trial 2H-2025 can provide data by Q2-2026

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# Tumor Microenvironment Modulators

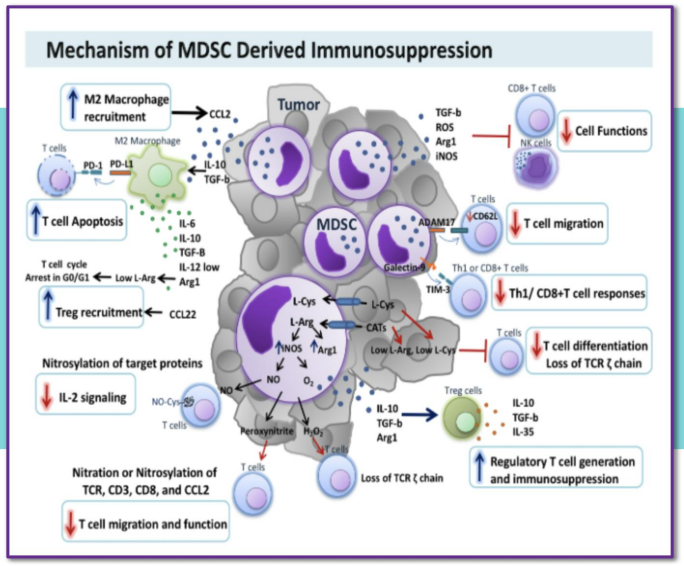
Novel Targets for Intervention

- Negative Immune Regulators (VISTA)
- MDSCs and M2 Macrophages (DOR inhibitors*)

*DOR – Delta Opioid Receptor

# MDSCs Create Immune Sanctuary for Tumors Causing Checkpoint Inhibitors and T Cell Therapies to Stop Working

- MDSCs are normally produced during pregnancy; provide immune sanctuary for fetus
- Hijacked by tumors, responsible for immunosuppression in TME
- Produce multiple immune suppressing factors (Arg-1, iNOS, TGFb,)
- Inhibit T cell proliferation and activation
- TuHURA and Moffitt scientists first to report expression of Delta Opioid Receptor on tumor associated MDSCs



# First-in-Class Immune Modulating Bi-Specific/Bi-Functional Antibody Drug or Antibody Peptide* Conjugates

***Single receptor target controls multiple pathways coupled to TME immune suppression***

| Delta Opioid Receptor (DOR) | Receptor Blockade with DOR Specific Antagonists** | First-in-class Immune Modulating ADCs and APCs |
|---|---|---|
| • Well characterized class of G-protein-coupled receptors (GPCRs)<br>• TuHURA and Moffitt Cancer Center scientists first to report over expression on tumor associated MDSCs and tumor polarized M2 macrophages | • Decreases MDSC and M2 macrophage production of multiple immunosuppressive factors (Arg-1, iNOS, IDO-1, VISTA, TGF-β)<br>• Significant improvement in overall survival in PD-1 resistant murine lung cancer model* | • Conjugates small molecule or peptidomimetic DOR inhibitor to a VISTA inhibiting mAb or other immune effectors<br>• Dual modality for inhibiting immunosuppressive phenotype of tumor microenvironment |

*peptidomimetic Delta Opioid Receptor specific inhibitor. ** McLaughlin, Rodriguez, Moffitt Cancer Center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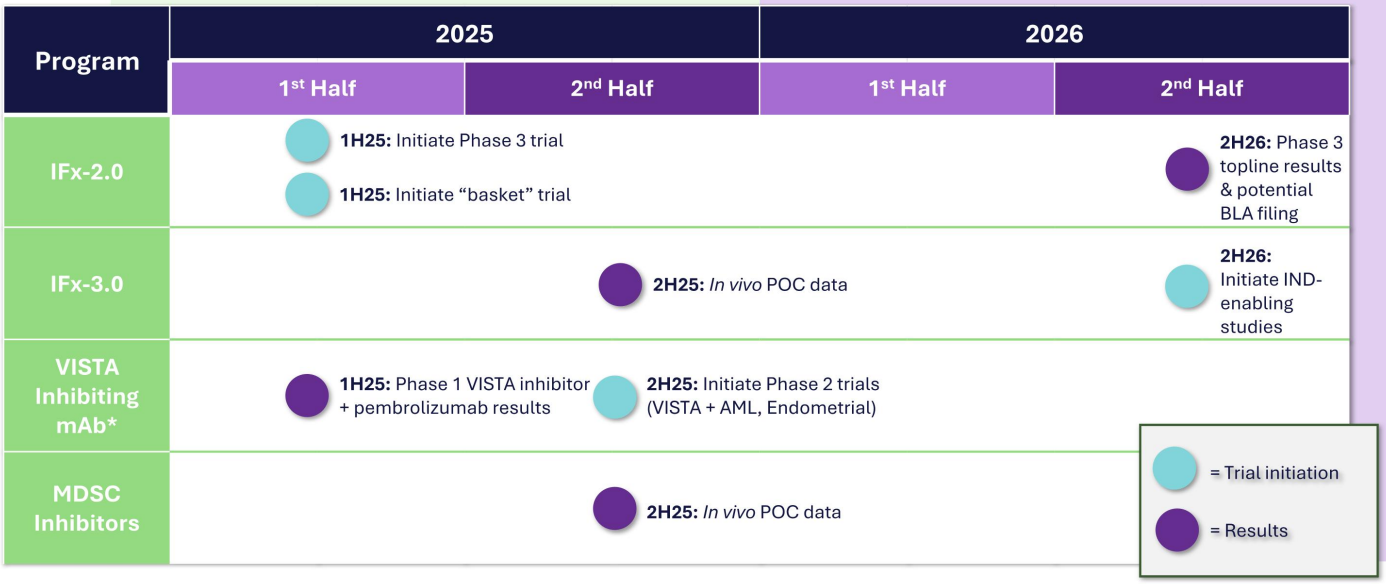
Corporate Highlights

# Upcoming Anticipated Milestones




* Subject to completion of acquisition anticipated in first half of 2025; currently subject to non-binding letter of intent

# Investment Summary

**Innate Immune Agonists**

✓ **Single Phase 3 registration directed Accelerated Approval trial for IFx-2.0***

- Demonstrated durable CRs and PRs in patients progressing on CPI in Phase 2 trial
- FDA Project Front Runner initiative encouraged trial in first line setting
- SPA Agreement with FDA on novel trial design could remove requirement for post approval confirmatory trial, potentially converting accelerated approval to full approval
- Top-line data anticipated 2H 2026

**Tumor Microenvironment Modulators**

✓ **Building a de-risked late-stage product pipeline**

- Definitive agreement to acquire by merger Kineta's VISTA inhibiting mAb in clinical partnership with Merck
- If completed, Kineta transaction adds Phase 2 stage candidate to development pipeline in NMP1 mutated AML
- First-in-class, non-tumor targeting, bi-specific immune modulating ADCs/APCs

**Business Highlights**

✓ **Clinical, corporate and regulatory milestones with 4 key data readouts expected over the next 24 months**

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* Trial currently subject to partial clinical hold relating to completion of certain CMC requirements for initiation of Phase 3 registration trial
MCC = Merkel cell carcinoma

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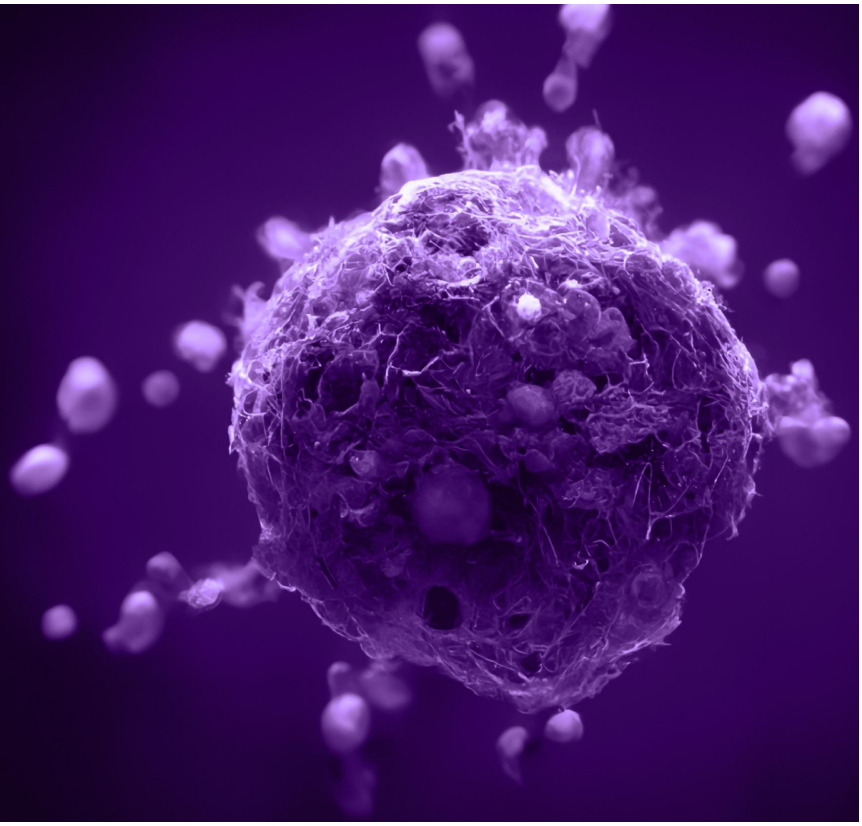
# Overcoming Resistance to Cancer Immunotherapy



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