TuHURA Biosciences, Inc. Reports Financial Results for Fiscal Year 2024 and Provides Corporate Update

Phase 3 IFx-2.0 accelerated approval trial as adjunctive therapy with Keytruda® (pembrolizumab) in 1st line therapy for advanced Merkel cell carcinoma (MCC) planning to initiate enrollment in Q2 2025

MCC Phase 3 trial to be conducted under Special Protocol Assessment (SPA) Agreement with FDA

Acquisition of Kineta's Phase 2 ready, VISTA inhibiting antibody targeted for completion in Q2 2025

Expanded discovery team for first-in-class immune modulating Antibody Drug or Peptide Conjugate Program

TAMPA, Fla., April 1, 2025 /PRNewswire/ -- **TuHURA Biosciences, Inc.** (NASDAQ:HURA) ("TuHURA" or the "Company"), a Phase 3 registration-stage immune-oncology company developing novel technologies to overcome resistance to cancer immunotherapy, today provided financial results for fiscal year 2024 and provided a corporate update.

"2024 was a transformative year for TuHURA. We became a NASDAQ-listed Company, raised capital to meet FDA's manufacturing requirements to initiate our Phase 3 program anticipated for Q2 as forecasted and entered into a definitive agreement for, what we believe, is a best-in-class VISTA inhibiting antibody adding a Phase 2 program in AML to our development pipeline," commented James Bianco, President and CEO of TuHURA. "As we advance our late stage clinical programs in 2025 with the goal of completing enrollment in our Phase 3 trial next year, we are also making significant progress in the development of the first novel class of non-tumor targeting Antibody Drug or Antibody Peptide Conjugates that are demonstrating the potential ability to remove the immunosuppressive functions of key cellular populations that create an immunologic sanctuary for tumors leading to acquired resistance to cancer immunotherapies."

2024 Highlights

- Successful SPA agreement with FDA
  - Single Phase 3 Accelerated Approval Trial[1]
  - Trial incorporates a key secondary endpoint (PFS) which, if achieved, may satisfy post approval confirmatory trial requirement
- Entered into definitive agreement with Kineta Inc. to acquire Phase 2 ready VISTA inhibitor; Transaction targeted to close in Q2 2025
- NASDAQ (HURA) listing via successful reverse merger with Kintara Therapeutics, Inc.
- Raised $36 million in 2024 to fund development programs and operations through late fourth quarter of 2025 and secure right to acquire VISTA inhibiting antibody

Advancing Novel Technologies to Overcome Resistance to Cancer Immunotherapy

Innate Immune Agonists: TuHURA's IFx technology utilizes a proprietary plasmid DNA or messenger RNA ("mRNA") which, when introduced into or targeted to a tumor, results in the expression of a highly immunogenic gram-positive, bacterial protein (Emm55) on the surface of the tumor cell, making the tumor look like a bacterium. Gram-positive bacterium has molecular patterns, or motifs, preserved over evolution which are recognized by receptors on our immune cells called "*toll like receptors*" (TLR). TLR 2 specifically recognizes the pattern of gram-positive bacterial proteins, like Emm55, leading to the activation of antigen presenting cells (APCs). Once activated, APCs digest the tumor cell and

present non-self, tumor neoantigens to newly produced T and B cells, activating a tumor-specific adaptive immune response. Through its activation of tumor-specific T cells, IFx-2.0 administration can potentially overcome primary resistance to checkpoint inhibitors.

TuHURA is preparing to initiate a single, randomized, placebo-controlled Phase 3 accelerated approval trial of IFx-2.0 administered as an adjunctive therapy to Keytruda® (pembrolizumab) versus pembrolizumab plus placebo in first line treatment for checkpoint inhibitor-naïve patients with advanced or metastatic MCC. The data from the Company's Phase 1b trial in patients with advanced or metastatic MCC who exhibited primary resistance to CPI was used to support a potential single registration directed trial. Consistent with the FDA's Project Front Runner Initiative, the FDA's Oncology Center of Excellence (OCE) recommended investigating IFx-2.0 in the first line setting rather than in patients progressing on first line therapy.

Project Front Runner is an FDA OCE initiative to encourage drug sponsors to consider when it may be appropriate to first develop and seek approval of new cancer drugs for advanced or metastatic disease, in an earlier clinical setting rather than the usual approach to develop and seek approval of a new drug for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options.

The FDA also requested the Company to consider designing the trial to include a key secondary endpoint shown to be of clinical benefit like PFS allowing this accelerated approval trial to potentially satisfy both the requirements for accelerated approval based on ORR, while satisfying the requirement for a post-approval confirmatory trial if the secondary PFS endpoint is achieved. The trial will be conducted under an SPA agreement with the FDA.

Tumor Microenvironment Modulators: Leveraging its delta opioid receptor technology, TuHURA is developing the first class of non-tumor targeting bi-specific immune modulating Antibody Drug Conjugates or Antibody Peptide Conjugates targeting MDSCs to inhibit their immune suppressing effects on the tumor microenvironment to prevent T cell exhaustion and acquired resistance to checkpoint inhibitors and cellular therapies.

Potential Acquisition of Novel Anti-VISTA Checkpoint Inhibitor: As previously announced, the Company entered into a definitive merger agreement in which TuHURA would acquire Kineta, Inc. (OTC Pink: KATN) including the rights to Kineta's novel KVA12123 antibody, for a combination of cash and shares of TuHURA common stock via a merger transaction. The merger is currently targeted to close in Q2 2025 pending the satisfaction of funding conditions and other closing conditions.

2025 Milestone Targets

- IFx-2.0
  - Q2: FDA complete response letter lifting partial clinical hold
  - Q2: Initiating enrollment in IFx-2.0 Phase 3 accelerated approval trial
  - Q3: Initiate checkpoint inhibitor resistant metastatic cancer "basket" trial
- IFx-3.0
  - Q4: Advance characterization toward lead compound selection
- VISTA Inhibiting mAb
  - Q2: Target closing of Kineta acquisition
  - Q2: Phase 1 VISTA inhibitor +/- pembrolizumab results
  - Q4: Initiate Phase 2 trial VISTA trial in NPM1 mutated AML
- Novel bi-specific non-tumor targeting immune modulating Antibody Drug or Antibody Peptide Conjugates
  - Advance delta opioid receptor technology platform
  - Presentations at key scientific meetings

Summary of Financial Results for the Full Year 2024

Research and development (R&D) expense was $13.3 million and $9.4 million for the years ended December 31, 2024

and 2023, respectively. The increase in R&D of $3.9 million is mainly related to:

- an increase of approximately $1.6 million due to ongoing clinical development of IFx-2.0;
- an increase of approximately $0.4 million due to preclinical research of IFx-3.0 and MDSCs; and
- an increase of approximately $1.9 million in salary and personnel related costs.

General and administrative (G&A) expenses were $4.3 million and $4.1 million for the years ended December 31, 2024 and 2023, respectively. The increase in G&A of $0.2 million was mainly attributable to increases in non-cash stock compensation expense and costs associated with being a public company incurred in 2024 offset by decrease in legal fees associated with the subsequently terminated proposed merger with CohBar, Inc. which were incurred in 2023.

About TuHURA Biosciences, Inc.

TuHURA Biosciences, Inc. (Nasdaq: HURA) is a Phase 3 registration-stage immuno-oncology company developing novel technologies to overcome primary and acquired resistance to cancer immunotherapy, two of the most common reasons cancer immunotherapies fail to work or stop working in the majority of patients with cancer.

TuHURA's lead innate immune agonist drug candidate, IFx-2.0, is designed to overcome primary resistance to checkpoint inhibitors. TuHURA is preparing to initiate in the second quarter 2025, a single randomized placebo-controlled Phase 3 registration=directed trial of IFx-2.0 administered as an adjunctive therapy to Keytruda® (pembrolizumab) compared to Keytruda® and placebo in first-line treatment for advanced or metastatic Merkel Cell Carcinoma.

In addition to its innate immune agonist candidates, following the anticipated closing of the previously announced proposed merger with Kineta, TuHURA plans to advance its VISTA inhibiting antibody into a phase two trial in combination with a menin inhibitor in NPM1 mutated relapsed or refractory AML. Leveraging its discovery of the central role the delta opioid receptor plays in modulating the immunosuppressive effects of myeloid derived suppressor cells (MDSCs) and tumor associated M2 polarized macrophages on the tumor microenvironment (TME), the Company is also developing non-tumor targeting ADCs and APCs to convert the TME to an immunogenic phenotype, potentially overcoming acquired resistance to checkpoint inhibitors and cellular therapies.

For more information, please visit tuhurabio.com and connect with TuHURA on Facebook, X, and LinkedIn.

IMPORTANT ADDITIONAL INFORMATION

In connection with the proposed acquisition by merger of Kineta, Inc. ("Kineta") by TuHURA (the "Merger"), TuHURA filed with the U.S. Securities and Exchange Commission (the "SEC") a registration statement on Form S-4, dated February 7, 2025 (the "Registration Statement"), which contains a preliminary joint proxy statement of Kineta and TuHURA and a preliminary prospectus of TuHURA (the "Joint Proxy Statement/Prospectus"), and TuHURA and Kineta may file with the SEC other relevant documents regarding the Merger. ***Investors and securityholders of TuHURA and Kineta are urged to read the Joint Proxy Statement/Prospectus and such other materials carefully when they become available because they will contain important information about TuHURA, Kineta, and the proposed Merger. This press release is not a substitute for the definitive Joint 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 Merger.***

A definitive copy of the Joint Proxy Statement/Prospectus will be mailed to Kineta and TuHURA stockholders when that document is final. 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 press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Merger 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 of 1933, as amended (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 Merger and other matters that may be set forth in the Joint Proxy Statement/Prospectus. Information about TuHURA's directors and executive officers is set forth in TuHURA's filings with the SEC, including TuHURA's Form 10-K filed on March 31, 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 Merger may be obtained by reading the Joint Proxy Statement/Prospectus when it becomes available. You may obtain free copies of these documents as described above under "IMPORTANT ADDITIONAL INFORMATION".

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This press release 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 of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These Forward-looking statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and other future conditions. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "should," "would," "project," "plan," "expect," "goal," "seek," "future," "likely" or the negative or plural of these words or similar expressions. Examples of such forward-looking statements include but are not limited to express or implied statements regarding TuHURA's expectations, hopes, beliefs, intentions or strategies regarding the future and include, without limitation, statements regarding statements about TuHURA's IFx-Hu2.0 product candidate and anticipate Phase 3 trial, 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, TuHURA's needs and expectations regarding its existing capital resources and its need for additional capital, and any developments or results in connection therewith and the anticipated regulatory pathway and timing of the foregoing development programs, studies and trials. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. You are cautioned that such statements are not guarantees of future performance and that actual results or developments may differ materially from those set forth in these forward-looking statements. Factors that could cause actual results to differ materially from these forward-looking statements are described in detail in our registration statements, reports and other filings with the SEC, which are available on the combined company's website, and at www.sec.gov.

The forward-looking statements and other information contained in this press release are made as of the date hereof, and TuHURA does not undertake any obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, unless so required by applicable securities laws. Nothing herein shall constitute an offer to sell or the solicitation of an offer to buy any securities.

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[1] Trial currently subject to partial clinical hold relating to completion of certain CMC requirements for initiation of Phase 3 registration trial

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