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# TuHURA Biosciences and Kineta Present Updated Results from Kineta's Phase I-II Study of KVA12123 and TuHURA's Mechanism of IFx-Hu2.0 Responses After Anti-PD-1 Therapy Failure in Advanced Melanoma at the American Association for Cancer Research Annual Meeting

*Kineta presents updated clinical data from VISTA-101 trial of KVA12123, demonstrating >90% VISTA receptor occupancy at 1,000mg dose level throughout the trial's every two weekly dosing interval (Q2W)*

*TuHURA's Phase 3-ready IFx2.0 produced clinically meaningful anti-tumor responses and abscopal effect, after checkpoint inhibitor (CPI) therapy failure in patients with advanced melanoma when rechallenged with CPI*

TAMPA, Fla., April 28, 2025 /PRNewswire/ --

TuHURA **Biosciences, Inc.** (NASDAQ:HURA) ("TuHURA"), a Phase 3 immune-oncology company developing novel technologies to overcome resistance to cancer immunotherapy, today reported on poster presentations of Kineta Inc.'s ("Kineta") KVA12123 novel anti-VISTA antibody and TuHURA's IFx-Hu2.0 in advanced melanoma and at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, IL.

In the first poster presentation, (CT041/20) TuHURA and Kineta provided updated results from VISTA-101, a Phase I-II first-in-human study of KVA12123 alone and in combination with pembrolizumab in patients with advanced solid tumors (NCT05708950). The poster, was presented by Thierry Guillaudeau, Ph.D., Chief Scientific Officer of Kineta. KVA12123 was found to be generally safe and well tolerated in all monotherapy and combination arms, with no dose-limiting toxicities observed. Additionally, KVA12123 demonstrated a favorable pharmacokinetic (PK) and pharmacodynamic (PD) profile at all dose levels, including:

- At 1,000mg every two weeks, KVA12123 demonstrated greater than dose proportional PK profile exceeding 90% VISTA receptor occupancy, providing important PK data for determining recommended Phase 2 dose.
- No dose limiting toxicities were observed in the study, including at the 1,000mg dose level, among the 24 patients treated in the monotherapy or in the 17 patients in the combination with pembrolizumab arms

"We are pleased to have Thierry present the latest data from the KVA12123 program, a valuable drug candidate that TuHURA will acquire following the closure of the proposed merger with Kineta which is currently targeted for the end of Q2 2025. TuHURA's exclusivity payment

last July allowed Kineta the ability to restart and complete the Phase I study providing important data regarding receptor occupancy and other PK, PD and translational biomarker data at the previously unstudied 1,000mg dose level. The study demonstrated in excess of 90% VISTA receptor occupancy over the entire Q2W dosing interval where PK simulations would predict similar receptor occupancy even at 750mg Q2W dosing, which we believe will be the recommended Phase 2 dose and schedule", stated James Bianco, M.D., President and Chief Executive Officer of TuHURA Biosciences.

Dr. Bianco continued, "Our primary interest in VISTA is its potential in immunologic tolerance in a variety of blood related cancers. Recent scientific data demonstrates that NPM1 mutation, present in 30% to 35% of patients with acute myeloid leukemia (AML) results in the high expression of VISTA on leukemic blasts. This is believed to be the mechanism by which leukemia escapes immune recognition and attack and is responsible for high rate of treatment failures in AML. We look forward to evaluating the VISTA inhibiting antibody in a Phase 2 randomized study in relapsed AML, which we expect to initiate in the fourth quarter of 2025 based on the anticipated closing of the proposed merger with Kineta."

TuHURA also announced that the Markowitz Lab at Moffitt Cancer Center also presented a poster of TuHURA's IFx-Hu2.0 in patients with advanced treatment refractory Melanoma who, like patients in TuHURA's Phase 1b Merkel cell carcinoma trial, progressed while on CPI therapy. The data demonstrated that, among heavily pre-treated patients with advanced Melanoma who were resistant to anti-PD-1-based therapy, following IFx-Hu2.0, three of four patients achieved clinically meaningful, durable anti-tumor responses following re-administration of a CPI.

"Demonstration of the development of antibody specific response to the Emm55 bacterial protein expressed on the surface of the tumor cell following IFx-Hu2.0 in the phase 1 study and an abscopal effect in murine model of melanoma is consistent with the data generated in patients with advanced cutaneous malignancies like melanoma or Merkel cell carcinoma," noted Dr. Bianco. "We look forward to that anticipated initiation of our Phase 3 accelerated approval trial in first line treatment of patients with advanced or metastatic Merkel cell carcinoma targeted for later this quarter."

In the second poster presentation relating to IFx-Hu2.0 entitled: "*Mechanistic Insights into IFx-Hu2.0 Responses in the First Human Trial After Prior Anti-PD-1 Therapy Failure*," (3428/23) IFx-Hu2.0's first-in-human study demonstrated stimulation of an innate immune response, with increased T cell and B cell production in peripheral blood compared to tumor tissue. This innate immune activation underscores the potential of IFx-Hu2.0 to generate tumor specific activate T and B cells for patients who are resistant to anti-PD-1 CPIs. Additionally, IFx-Hu2.0 was generally safe and well tolerated, with only mild Grade 1 and Grade 2 adverse events, largely injection site reactions.

As previously announced, on December 11, 2024, TuHURA entered into a definitive agreement with Kineta, Inc. (OTC Pink: KANT) ("Kineta"), in which TuHURA agreed to acquire Kineta, including the rights to Kineta's novel KVA12123 antibody, for a combination of cash and shares of TuHURA common stock via a merger transaction upon the terms and conditions and subject to the conditions set forth in TuHURA's Form 8-K filed on December 12, 2024. The merger is currently targeted to close in Q2 2025 pending the satisfaction of certain closing conditions.

### **About TuHURA Biosciences, Inc.**

TuHURA Biosciences, Inc. (Nasdaq: HURA) is a Phase 3 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, IFx-2.0, is designed to overcome primary resistance to checkpoint inhibitors. TuHURA is preparing to initiate a single randomized placebo-controlled Phase 3 registration trial of IFx-2.0 administered as an adjunctive therapy to Keytruda<sup>®</sup> (pembrolizumab) compared to Keytruda<sup>®</sup> plus placebo in first line treatment for advanced or metastatic Merkel Cell Carcinoma.

In addition to its innate immune agonist product candidates, TuHURA is leveraging its Delta Opioid Receptor technology to develop first-in-class, bi-specific antibody drug conjugates and antibody peptide conjugates targeting Myeloid Derived Suppressor Cells to inhibit their immune-suppressing effects on the tumor microenvironment to prevent T cell exhaustion and acquired resistance to checkpoint inhibitors and cellular therapies.

For more information, please visit [www.tuhurabio.com](http://www.tuhurabio.com) and connect with TuHURA on [Facebook](#), [X](#), and [LinkedIn](#).

## **IMPORTANT ADDITIONAL INFORMATION**

In connection with the proposed acquisition by merger (the "Merger") of Kineta, Inc. ("Kineta") by TuHURA Sciences, Inc. ("TuHURA"), 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](http://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](http://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.

## **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 TuHURA's IFx-Hu2.0 product candidate and anticipated Phase 3 trial, 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 statements regarding the closing conditions for the transaction, 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](http://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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