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TuHURA Biosciences Initiates Its Phase 3 Accelerated Approval Trial of IFx-2.0 as an Adjunctive Therapy to Keytruda® (pembrolizumab) in First Line Treatment for Advanced or Metastatic Merkel Cell Carcinoma

Phase 3 trial being conducted under a Special Protocol Assessment (SPA) agreement with U.S. Food and Drug Administration (FDA)

Primary endpoint of Overall Response Rate (ORR) qualifies for accelerated approval process

Key secondary endpoint of Progression Free Survival (PFS) may satisfy the requirement for a post confirmatory trial, converting accelerated approval to regular approval

Initiation of the Phase 3 accelerated approval trial unlocks the third tranche of funds from \$12.5 million PIPE financing announced on June 3, 2025

TAMPA, Fla., June 24, 2025 /PRNewswire/ -- **TuHURA Biosciences, Inc.** (NASDAQ:HURA) ("TuHURA" or the "Company"), a Phase 3 immune-oncology company developing novel technologies to overcome resistance to cancer immunotherapy, today announced the initiation of its Phase 3 accelerated approval trial of IFx-2.0, TuHURA's lead innate immune agonist, in patients with advanced or metastatic Merkel cell carcinoma (MCC).

IFx-2.0 is designed to overcome primary resistance to checkpoint inhibitors (CPIs), such as Keytruda® (pembrolizumab), and has demonstrated systemic anti-tumor specific immune responses (an abscopal effect) when administered intratumorally into cutaneous, subcutaneous, or accessible nodal lesions in the Company's Phase 1b trial of IFx-2.0 in patients with advanced or metastatic MCC. In the Phase 1b trial, patients with advanced or metastatic MCC who progressed on either pembrolizumab or avelumab (anti-PD(L)-1) therapy, received weekly administration of IFx-2.0 for up to three doses followed by rechallenge with anti-PD(L)-1 therapy. Results demonstrated an overall response rate of 63% (2 CR, 5 PR) with two responses lasting 23 and 33 months and five ongoing responses (6, 11, 13, 19 and 23 months) as of the last follow-up.

"The initiation of IFx-2.0's Phase 3 accelerated approval trial is a significant milestone for TuHURA and for the 40% to 50% of patients with advanced or metastatic MCC who may not respond to first line treatment with Keytruda[®] (pembrolizumab)," stated James Bianco, M.D., President and Chief Executive Officer of TuHURA Biosciences. "IFx-2.0's potential ability to harness the power of a patient's innate immune response leading to the activation and proliferation of tumor specific B cells and T cells represents a novel mechanism to overcome primary resistance to checkpoint inhibitors. As we start initiating study sites, we are grateful for the interest among investigators from leading cancer centers across the US in participating in this Phase 3 trial. We anticipate having more than half of the 22 participating sites open over the next 3-4 weeks, with the balance activated by the end of summer."

The Company's Phase 3 accelerated approval trial of IFx-2.0, conducted under an SPA Agreement with the U.S. FDA, will evaluate IFx-2.0 as an adjunctive therapy administered weekly for three weeks concurrent with the approved dose and schedule for Keytruda[®] compared to Keytruda[®] plus placebo in the first line treatment for patients with advanced or metastatic MCC. Keytruda[®] is currently approved in MCC under accelerated approval based on ORR. The pivotal trial for IFx-2.0 is expected to enroll 118 participants across approximately 22 to 25 U.S. sites. Trial participants will be randomized on a 1:1 basis and receive Keytruda[®] in both arms, for up to two years, or until disease progression or Keytruda[®] related toxicities. The primary endpoint for the trial is ORR with a key secondary endpoint of PFS. Other secondary endpoints are safety, duration of response, and overall survival. Accelerated approval is based on the successful achievement of the ORR primary endpoint. The key secondary endpoint of PFS, if successfully achieved without a detrimental effect on overall survival, could satisfy the requirement for regular approval without the requirement for a post approval confirmatory trial.

The initiation of the Phase 3 trial represents the achievement of a milestone for the third tranche of funding under the Company's recently announced private placement, thereby triggering the purchase from the Company of an additional \$2.23 million under the private placement financing.

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. In June 2025, TuHURA initiated a single randomized placebo-controlled Phase 3 registration trial of IFx-2.0 administered as an adjunctive therapy to Keytruda[®] (pembrolizumab) compared to Keytruda[®] plus placebo in first-line treatment for advanced or metastatic Merkel Cell Carcinoma.

Following the anticipated closing of the Company's acquisition by merger of Kineta, Inc., the Company expects to advance its novel VISTA inhibiting antibody into a randomized Phase 2 trial in NPM1 mutated r/r AML in combination with a menin inhibitor. Recent reports demonstrate that NPM1, the most common mutation in AML, increases the expression of VISTA on leukemic blasts resulting in escape of immune recognition and attack leading to

low response rate and persistence or relapse following current therapies, including menin inhibitors.

In addition to its innate immune agonist and VISTA inhibiting 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 and connect with TuHURA on [Facebook](#), [X](#), and [LinkedIn](#).

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 Phase 3 trial, its tumor microenvironment modulators development program, its anticipated acquisition by merger of Kineta Inc. and the statements about Kineta's VISTA-101 development program, and any developments or results in connection with the foregoing 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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