

August 14, 2025



TuHURA Biosciences, Inc. Reports Second Quarter 2025 Financial Results and Provides a Corporate Update

Completed the acquisition of Kineta, Inc. and its VISTA inhibiting monoclonal antibody (mAb), now named "TBS-2025;" planning to initiate a Phase 2 trial in relapsed/refractory NPM1-mutated Acute Myeloid Leukemia (AML) in combination with a menin inhibitor in 2H 2025

Initiated a Phase 3 accelerated approval trial of IFx-2.0 as adjunctive therapy with Keytruda® (pembrolizumab) as a first-line therapy for advanced and metastatic Merkel cell carcinoma (MCC), conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA)

Completed a \$12.5 million equity financing transaction, and received an additional \$3 million in warrant exercise proceeds

TAMPA, Fla., Aug. 14, 2025 /PRNewswire/ -- **TuHURA Biosciences, Inc.** (NASDAQ: HURA) ("TuHURA" or the "Company"), a Phase 3 immuno-oncology company developing novel technologies to overcome resistance to cancer immunotherapy, today reported financial results for the Company's second quarter ended June 30, 2025, and provided a corporate update.

"TuHURA had a strong first-half of the year with the initiation of its Phase 3 accelerated approval trial of IFx-2.0 as an adjunctive therapy to pembrolizumab as a first line treatment for patients with advanced or metastatic MCC. Conducted under an SPA Agreement with the FDA, the Phase 3 trial is a single randomized placebo-controlled trial that, if successful, has the potential to both meet and satisfy the requirements for both accelerated and full approval without the need to conduct a post-accelerated approval confirmatory trial. This potentially translates to a meaningful time and cost savings to TuHURA," stated James Bianco, M.D., President and Chief Executive Officer of TuHURA. "In addition to our accelerated approval Phase 3 trial of IFx-2.0, we also initiated a Phase 1b/2a trial employing interventional radiologic administration of IFx-2.0 as an adjunctive therapy to pembrolizumab in first-line treatment of checkpoint-naïve patients with MCC of unknown primary origin (MCCUP). This trial will enroll newly diagnosed patients who present metastatic, deep-seated tumors in the liver, lungs, or retroperitoneum, without accessible cutaneous, subdermal or nodal lesions. Patients with MCCUP represent approximately a thirty percent (30%) of all newly diagnosed advanced or metastatic MCC cases and can meaningfully augment IFx-2.0's commercial market opportunity."

Dr. Bianco continued, "In addition to our trial initiations in MCC and MCCUP, we recently bolstered our development pipeline with the acquisition of Kineta and their novel VISTA

inhibiting antibody, TBS-2025. The acquisition provides for synergies across both TuHURA's therapeutic focus as well as TuHURA's antibody peptide or drug candidate (APC, ADC) technologies as we continue to assemble a diversified, late-stage immuno-oncology pipeline. We plan to advance TBS-2025 into a randomized Phase 2 trial in patients with relapsed or refractory *NPM1*-mutated AML planned for the second half of this year to determine if the addition of TBS-2025 to a menin inhibitor can improve the results seen in patients receiving a menin inhibitor."

Corporate Highlights

- **Inclusion of TuHURA Biosciences in the Russell 3000[®] and Russell 2000[®] Indexes.** In June 2025, TuHURA announced its addition to the Russell 3000[®] Index, with automatic inclusion in the Russell 2000[®] Index, as a part of the 2025 Russell annual reconstitution. The Company's addition was effective as of market close on June 27, 2025.
- **Completion of Kineta, Inc. Acquisition and Kineta's VISTA Inhibiting mAb.** In June 2025, TuHURA announced the closing of its acquisition of Kineta, and Kineta's novel VISTA inhibiting mAb, now referred to as "TBS-2025." TuHURA plans to initiate a Phase 2 randomized trial of TBS-2025 in combination with a menin inhibitor for the treatment of relapsed or refractory *NPM1*-mutated AML, compared to a menin inhibitor alone, targeted for the second half of 2025.
- **Initiation of Phase 3 Accelerated Approval Trial of IFx-2.0 as Adjunctive Therapy to Keytruda in 1L MCC.** In June 2025, TuHURA announced that it had initiated its Phase 3 accelerated approval trial of IFx-2.0 as an adjunctive therapy to pembrolizumab in MCC. Conducted under an SPA agreement with the U.S. FDA, TuHURA is investigating the effectiveness of IFx-2.0 as an adjunctive therapy to Keytruda[®] compared to Keytruda[®] plus placebo in first line treatment in advanced or metastatic MCC.
- **Completed \$12.5 Million Equity Financing Transaction and Received an Additional \$3.0 Million in Warrant Exercise Proceeds.** In June 2025, TuHURA announced that it had entered into a definitive securities purchase agreement for the issuance and sale in a private placement of an aggregate of \$12.5 million shares of its common stock. In addition to the offering, the Company secured \$3.0 million in additional cash proceeds from the previously disclosed February 2025 cash exercise of approximately 1.0 million warrants to purchase shares of the Company common stock.

Upcoming Targeted Milestones by Program

IFx-2.0

- Year-End 2025: TuHURA anticipates providing an update on enrollment progress in its Phase 3 accelerated approval trial of IFx-2.0 as an adjunctive therapy to pembrolizumab in first line MCC
- Q1 2026: Anticipated topline results from Phase 1b/2a clinical trial of IFx-2.0 as an adjunctive therapy to pembrolizumab in first line treatment for MCC of unknown primary origin (MCCUP)
- 2H 2026: Anticipated topline results from Phase 3 accelerated approval trial

TBS-2025

- 2H 2025: Planned initiation of Phase 2 trial of VISTA inhibiting mAb in combination with a menin inhibitor for the treatment of relapsed or refractory NPM1-mutated AML

APC and ADC Development Candidates

- TuHURA continues to advance its bi-specific, bi-functional immune modulating ADCs and APCs that target the Delta Opioid Receptor (DOR) on MDSCs, inhibiting their immune suppressing effects in the tumor microenvironment while localizing a checkpoint inhibitor like TBS-2025
- In 2025, TuHURA anticipates presenting non-clinical data at relevant medical meetings

Financial Results for the Three Months and Six Months Ended June 30, 2025

Research and development expenses were \$4.9 million and \$2.8 million for the three months ended June 30, 2025, and 2024, respectively.

Net cash outflows from operating activities were (\$10.9) million and (\$8.9) million for the six months ended June 30, 2025, and 2024, respectively.

As of June 30, 2025, TuHURA's total shares outstanding was approximately 49.9 million.

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.

In addition to its innate immune agonist product candidates, TuHURA acquired TBS-2025 in the merger with Kineta on June 30, 2025. TBS-2025 is a VISTA inhibiting mAb asset moving into Phase 2 development in mutNPM1 r/r AML. In addition, 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 Delta Opioid Receptor technology, its recent acquisition by merger of Kineta Inc., 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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