February 17, 2026

TuHURA Files Investigational New Drug Application for TBS-2025 in the Treatment of Blood-Related Cancers

TBS-2025 to be investigated in combination with a menin inhibitor in mutNPM1 r/r AML

TAMPA, Fla., Feb. 17, 2026 /PRNewswire/ -- TuHURA Biosciences, Inc. (NASDAQ:HURA) ("TuHURA" or the "Company"), a Phase 3 immuno-oncology company developing novel therapeutics to overcome resistance to cancer immunotherapy, today announced that it has filed an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration's (FDA) Division of Hematologic Malignancies 1 (DHM1) for the study of TBS-2025, a novel VISTA inhibiting antibody, for the treatment of *mut*NPM1 relapsed/refractory (r/r) Acute Myeloid Leukemia (AML) in combination with a menin inhibitor.

The Company plans on initiating a Phase 2 study in menin inhibitor naïve patients with *mut*NPM1 r/r AML utilizing a Simon 2 stage design. Pending completion of FDA review and clearance, the Company currently targets initiating the Phase 2 study in early Q2 2026 with preliminary Stage 1 results in Q3 2026.

"There is a broad body of scientific evidence showing that leukemogenic mutations common in AML, such as *mut*NPM1, may drive the expression of VISTA on the surface of leukemic cells, which contribute to low response rates to therapy and markedly reduced overall survival," said Dr. James Bianco, President and Chief Executive Officer of TuHURA Biosciences.

"While the introduction of menin inhibitors for the treatment of *mut*NPM1 r/r AML has provided these patients with the first approved therapy, CR/CRh rates across the class are generally <25% and of short duration, underscoring the continued unmet medical need." Dr. Bianco continued, "Given the strong scientific rationale, we believe adding TBS-2025 to a menin inhibitor may markedly increase both the CR/CRh rate and its duration, potentially addressing this unmet medical need. If successful, the Company would seek FDA guidance on the potential for developing TBS-2025 under FDA's accelerated approval pathway."

About TBS-2025
TBS-2025 is a unique VISTA-inhibiting monoclonal antibody acquired by the Company in its acquisition by merger with Kineta Inc. on June 30, 2025. VISTA is a novel checkpoint expressed on quiescent (resting) T cells and highly expressed on myeloid cells. Unlike the expression of VISTA on solid tumor cancers, its role is well established in hematological malignancies. Scientific evidence demonstrates that *mut*NPM1 and *mut*DNM3TA, two of the most common mutations in AML and other myeloid (blood related) malignancies, may drive the expression of VISTA on leukemic blasts and are reported to be the primary mechanisms by which AML has a poor response to and high relapse rate following current therapies. VISTA expression is linked to high relapse rates in AML due to its ability to allow leukemic

blasts to evade immune recognition and attack by the patient's immune system. When VSIR, the gene that encodes for VISTA, is removed in murine models of *mut*NPM1 AML, an immune response is observed and survival is enhanced.

TBS-2025 was initially investigated by Kineta in a large Phase 1 trial either as monotherapy (n=24) or in combination with pembrolizumab (n=15) among patients with advanced, therapy refractory cancers, including breast, lung, colorectal, and ovarian cancer. The purpose of the study was to investigate its safety profile and determine the recommended Phase 2 dose. The drug demonstrated a favorable safety profile even at the highest dose level of 1,000mg administered every two weeks. Based on pharmacokinetics and pharmacodynamics, the Company believes the optimal Phase 2 dose is 750mg every three weeks.

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 has 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 its acquisition by merger with Kineta Inc. on June 30, 2025. TBS-2025 is a VISTA inhibiting mAb moving into Phase 2 development in *mut*NPM1 r/r AML. In addition, TuHURA is leveraging its Delta Opioid Receptor technology to develop first-in-class, bi-specific, bi-functional antibody drug conjugates (ADCs) 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. 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 TuHURA'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.

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