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TuHURA Biosciences Files Investigational New Drug Application for Evaluation of the TBS-2025 VISTA Inhibiting Antibody in Molecularly Defined Subsets of AML and Other Blood Related Cancers

The IND is aligned with guidance previously provided by the U.S. Food and Drug Administration (FDA) on the development pathway for both monotherapy and combination with menin inhibitors for Acute Myeloid Leukemia (AML)

The FDA noted that the requested meeting would not be necessary and that it will instead provide written responses to questions and information related to the Company's proposed Phase 1b/2 development plan for TBS-2025 in AML

The Company is targeting initiation of the Phase 1b/2 study in the second half of 2026

TAMPA, Fla., June 15, 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 (IND) application with the U.S. Food and Drug Administration (FDA) for the study of its TBS-2025 VISTA inhibiting antibody for the treatment of molecularly defined subsets of AML and other blood related cancers. The IND is being filed following detailed feedback and guidance from the FDA on the IND filed in February 2026.

"We are excited to be the first company to advance a VISTA-inhibiting antibody for investigation in hematologic cancers, targeting molecularly defined subsets of AML, including those with NPM1 and in the future, FLT3-ITD mutations, two of the most common mutations present in approximately 60-70% of patients with AML. We also plan to include patients with relapsed/refractory (r/r) high-risk myelodysplasia (MDS), where VISTA expression, like in AML, generally correlates with low response rates and poor survival outcomes," said Dr. James Bianco, President and Chief Executive Officer of TuHURA Biosciences. "Currently, there are no approved or effective treatment options for these patient populations, representing a significant unmet medical need."

Dr. Craig Tendler, Chief Medical Officer consultant overseeing the TBS-2025 development program and Board member of TuHURA Biosciences, added, "The FDA provided valuable feedback and comprehensive guidance on trial design, which we incorporated into our proposed Phase1b dose optimization trial. Our plan is to combine the Phase 1b with the Phase 2 study for a combination study design that is much more efficient and could

potentially save 4-6 months in development time. We look forward to FDA's written responses anticipated to be received next month and, depending on the responses, are targeting initiating the Phase 1b/2 trial of TBS-2025 in the second half of 2026."

The Phase 1b portion of the study will examine the safety and potential efficacy of monotherapy dose levels in relapsed/refractory (r/r) AML patients, most of whom will harbor the NPM1 mutation and have failed to respond or relapsed after menin inhibitor therapy. In the planned protocol, if a safe and biologically effective dose is identified, the Company will review the data with the FDA to discuss the potential to expand the study at a recommended Phase 2 dose determined in the Phase 1b, to pursue a potential accelerated approval pathway, a development path similar to that of menin inhibitors in this molecular subset of patients with r/r *mut*NPM1 AML.

It is anticipated that the Phase 2 portion of the study will explore the potential of TBS-2025 to improve complete response rates and duration of response when used in combination with menin inhibitors in patients with *mut*NPM1 r/r AML.

About TBS-2025
TBS-2025 is a unique VISTA-inhibiting monoclonal antibody. VISTA is a novel checkpoint expressed on quiescent (resting) T cells and highly expressed on myeloid cells, notably myeloid derived suppressor cells (MDSCs). Scientific evidence demonstrates that *mut*NPM1 has demonstrated the mutation drives the expression of VISTA on leukemic blasts, which is reported to be the primary mechanisms by which AML escapes recognition by the patient's immune system, resulting in low response rates of short duration following current therapies, including recently approved menin inhibitors. 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. Similarly, in a murine model of AML, TBS-2025 resulted in an increase in survival comparable to intensive chemotherapy regimen that is currently used in front line treatment of patients with AML. When combined with intensive chemotherapy, survival was markedly improved. Collectively, these data underscore the potential for TBS-2025 in the treatment of patients with AML

TBS 2025 was initially investigated in a large Phase 1 trial as either 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 for solid tumors. The drug demonstrated a favorable safety profile even at the highest dose level of 1,000mg administered every two weeks. Safety and pharmacokinetic data from this trial was helpful in designing the Phase 1b segment of the planned trial in AML.

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 is developing TBS-2025, a VISTA inhibiting mAb moving into Phase 1b/2 in *mut*NPM1 r/r AML, a molecularly defined subgroup of patients with AML. TuHURA is also leveraging its Delta Opioid Receptor technology to develop first-in-class, bi-specific, bi-functional antibody drug conjugates (ADCs) 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.

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 of 1933, as amended, Section 21E of the Securities 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 include, among others: the risks relating to the timing and nature of the FDA's response to the Company's re-filed IND for TBS-2025; the risks associated with the timing and results of conducting the planned Phase 1b/2 trial of TBS-2025, including the risks related to patient enrollment, trial design, data outcomes and regulatory interactions; uncertainty regarding the timing and likelihood of regulatory approvals; and the other risks described from time to time in detail in Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as filed on March 31, 2026, and TuHURA's other reports and filings with the SEC from time to time, 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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