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Requests for Expanded Access to Investigational (Unapproved) Drugs

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This Policy for Requests for Expanded Access to Investigational Drugs describes the principles and procedures that Kintara Therapeutics, Inc. ("Kintara" or "the Company") will follow when considering requests by licensed physicians for use of Kintara's investigational drugs outside of clinical trials in accordance with the requirements of the 21st Century Cures Act and other legal and regulatory obligations. Please see below for further details. "Expanded Access" is also sometimes referred to as "Compassionate Use" or "Preapproval Access".

This policy is not a guarantee of access to any specific investigational drug by any individual patient. The decision to approve an Expanded Access request is at the sole discretion of Kintara and the Company shall have no liability in approving or denying such requests. This policy may be revised by Kintara at any time.

I. Kintara Policy for Evaluating Expanded Access to Investigational Drugs not Provided Through Kintara Clinical Trials

Kintara is currently testing in clinical trials their investigational drugs that have not yet been approved by the US Food and Drug Administration (FDA) for commercial sale. We have conducted and are conducting research on our investigational drugs so that we can better understand how these investigational drugs work, obtain proof that they are safe and effective, and win approval from FDA and other international regulatory authorities to make these drugs available commercially. Our scientific and ethical obligations to our patients, healthcare professionals and stakeholders are to conduct this clinical research as quickly and efficiently as possible.

On rare occasions, physicians may identify patients with serious diseases or conditions who cannot participate in our clinical trials but who may benefit from one of our investigational drugs despite its lack of demonstrated safety and effectiveness. In such situations, Kintara will on a

case by case basis consider requests from physicians for a supply of investigational drug to use with a specifically identified patient.

Kintara will evaluate such requests in a scientifically and ethically responsible way according to the principles and procedures set forth below and applicable government regulations.

1. **The investigational drug must be in active clinical development.** Kintara must be actively studying the investigational therapy in Phase 2 or Phase 3 clinical trials in the United States conducted under an IND filed with the FDA or in Phase 2 or Phase 3 clinical trials in the European Union under an equivalent application filed with the European Medicines Agency. In considering applications for and providing expanded access therapy to patients outside the United States, Kintara is required to abide by local government laws and health authority regulatory guidelines.

2. **The patient must have a serious disease or condition.**

3. **The request for use of the investigation drug must be within the requirements set forth by FDA in 21CFR, part 312 and must be within the scope of Kintara's current research interests as determined by Kintara in its sole discretion, including but not limited to uses being studied in Kintara's clinical trials or prior Phase 2 or Phase 3 trials conducted by Kintara or the US National Cancer Institutes.**

4. **Patients must have tried to join our clinical trials of the investigational drug.** Clinical trials are the customary way in which patients access investigation drugs. Kintara has a scientific and ethical obligation to complete clinical trials, win FDA approval of our drugs, and offer their benefit to a wider population of patients.

   Clinical trials are conducted by investigators trained on the use of and risks of our investigational drugs. Therefore, as a precondition for any request for access to a Kintara investigational outside of clinical trials in a disease indication currently being studied by Kintara in a clinical trial, a physician must try to enroll a patient in a clinical trial of the investigational drug. If however, it is clear that a patient does not meet the criteria for participation in the clinical trial or is unable to participate in the trial for geographic reasons, this requirement may be waived.

5. **There must be a positive benefit-risk ratio for the patient based on the treating physician's medical judgement. The potential benefits to the patient seeking access to the investigational drug must always outweigh the collective potential risks to the patient.** Establishing a positive risk-benefit is the responsibility of the treating physician. Kintara will provide information on current experience with the drug and it will be the treating

physician's responsibility to provide sufficient information to allow Kintara, in its sole discretion, to make an informed decision on the potential risks to the patient based on knowledge of the drug to date. As the drug is still in investigational stages of development, no claims on the risk-benefit to the patient can be made by Kintara. While the decision to make an investigational drug available shall be made solely at Kintara's discretion, Kintara shall rely on information provided by the treating physician in making its decision and shall have no liability in approving or denying such requests.

6. **The physician requesting access must be licensed and qualified to prescribe, and if applicable administer the investigational drug, agree to directly supervise treatment, be willing to obtain an IND from FDA, otherwise comply with relevant US federal, state, international, and institutional regulations, and agree to follow Kintara policies applicable to expanded use in general and any conditions or restrictions set by Kintara for the particular drug and patient.** To facilitate this process, Kintara will provide a Letter of Authorization to allow FDA or other regulatory authorities to reference the Company's investigational new drug (IND) application for approved Expanded Access applications.

7. **The physician requesting access must provide:**
   - A persuasive scientific rationale for the theoretical benefit that the investigational drug could provide;
   - A statement that all approved therapies typically used to treat the disease have been exhausted and the patient is no longer responsive to, or able to tolerate, these therapies;
   - A statement that there are no other viable therapy options, including participation in ongoing relevant clinical trials; and
   - Statement promising to provide copies of all reports on safety and SAE to Kintara.

8. **There must be sufficient clinical data to identify an appropriate dose (amount and frequency of the investigational drug given) and appropriate formulation.** In the absence of such data, the treating physician must provide adequate rationale for use, including any dosing regimen previously untried.

9. **After meeting the needs of clinical trials and other patients, Kintara must have a sufficient supply of the investigational drug to reasonably accommodate the likely duration of treatment.**

10. **The physician and patient must agree to waive claims for damages against Kintara.**

II. Procedure for Requesting Expanded Access and Response Times

1. **Treating physicians interested in treating a patient with a Kintara investigational drug that is in active clinical development must fill out the FDA Individual Expanded Access Application for FDA3926 and acknowledgement: Information on obtaining form FDA3926 can be found here.** This form must be submitted to Kintara for review using the instructions below.

2. **When the form has been satisfactorily completed and submitted to Kintara, the Company will seek to acknowledge receipt via email within 48 hours of submission of the request.**

3. **Making a request does not guarantee the granting of access to an investigational drug. Kintara will review each request on a case by case basis and will usually make a decision to grant or deny it or ask for more information within 10 business days. The decision to grant access is solely Kintara's decision.**

III. Contact for Further Information

Persons with questions about Kintara's policy and procedures for expanded access or about expanded access to Kintara investigational drugs may send an email to the following address:

John Langlands jlanglands@Kintara.com

Further information about Kintara's clinical trials is available at www.Kintara.com and on the NIH's ClinicalTrials.gov website.