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Policy on Offering Compassionate Use to Investigational Medicines

Telix Pharmaceuticals Limited and its international operating subsidiaries (“Telix”, “Company”) is focused on developing diagnostic and therapeutic products based on “molecularly targeted radiation” (MTR) technology. MTR products are typically administered to patients by specialist physicians and we work closely with leading cancer centres to make a positive impact on patient care. To do this, we conduct clinical trials to assess the safety and efficacy of investigational medicines, which if proven, will allow us to obtain the necessary approvals from regulatory authorities to provide patients with broad access to these medicines. Typically, clinical trials are sponsored (funded) and controlled by the Company but in certain instances we also allow academic key opinion leaders (KOLs) to run investigator-sponsored studies.

In general, Telix believes that participating in clinical trials is the most appropriate way for patients to access medicines prior to regulatory approval and marketing authorization. In some extreme circumstances when this is not possible, patients with life-threatening conditions may seek special access to investigational medicines outside of a formal clinical trial setting. This is particularly the case for Telix’s glioblastoma program, which is a highly aggressive form of cancer with a very poor prognosis. These situations are typically referred to as compassionate use, but can also be known as expanded access, early access, pre-approval access and emergency use.

A typical clinical development process involves controlled testing in humans to ensure both safety and efficacy, with full oversight from a regulatory body such as the Therapeutic Goods Administration (TGA) or the US Food and Drug Administration (FDA). Because it is not fully understood in clinical development whether an investigational medicine is safe or effective, compassionate use may present significant risks for the patient and for the clinical development program. For patients, compassionate use may bring potential safety risks or a false sense that the medicine will provide benefit; for the clinical development program, it can delay or undermine the approval of a new medicine sought by many.

Conducting clinical trials is extremely complex and difficult. The ultimate goal is the rigorous testing of the clinical product with the aim of securing regulatory approval and enabling a medicine to be available to as many patients as possible as quickly as possible. Telix has ethical responsibilities to ensure the quality and integrity of clinical trials and to minimize the risk to both current research participants and future patients. These ethical responsibilities require that strict criteria are applied for compassionate use of our investigational medicines.

We consider many factors when considering a request for compassionate use of an investigational medicine, such as the strength of the clinical data, the risk-benefit profile of the patient, the potential impact on the clinical development program, the phase of development, and probability and timing of regulatory approval. In addition, because we are developing radioactive drugs, there are significant production and logistics challenges that may limit the geographic availability of an investigational medicine, irrespective of the merit of

compassionate use availability. At Telix, a compassionate use program, or a single request for compassionate use of an investigational medicine, can only be considered if all of the following conditions are met:

1. The patient's condition is immediately life-threatening.
2. There are no adequate alternative therapies or clinical trials available to the patient.
3. Sufficient preliminary efficacy and safety data exist for the drug in order for Telix to determine a risk-benefit analysis that is consistent with the establishment of a compassionate use program. This would likely not occur earlier than the commencement of Phase II studies and, depending on the clinical program, potentially even later.
4. Sufficient clinical data is available to identify an appropriate dose / dosing regimen.
5. A patient's treating physician and Telix's clinical team both believe there is the potential for the specific patient under consideration to reasonably expect benefit from the treatment, and there is robust evidence to support the possibility that the patient will benefit.
6. Adequate supply exists to support both the ongoing clinical trials and approved compassionate use, until and if an investigational medicine becomes commercially available.
7. The patient is not eligible or a candidate for one of the Telix-sponsored studies on the therapy. Geographic limitations to participate in a trial would typically not mean a patient is ineligible.
8. Compassionate access will not adversely impact the clinical development program, in particular, the conduct of a pivotal clinical trial that is required for regulatory approval.
9. The request must be made by the patient's treating physician, unsolicited by Telix or any other individual or organization.

The above criteria are those that Telix will consider in determining whether to offer compassionate use; however, Telix cannot make a guarantee that a compassionate use program will be available, and, even if a compassionate use program is offered, Telix cannot make a guarantee that the investigational medicine will be available to a particular patient in a timely fashion.

If all these conditions are met, Telix will consider compassionate use requests from treating physicians subject to local/national laws and regulations. Receipt of a request will be acknowledged within three (3) business days. All requests will be evaluated in a fair, unbiased manner. Patients with exceptional safety risks that have not been adequately studied would be excluded. Any pre-approval access to investigational product must always comply with the applicable country-specific laws and regulations, including (but not limited to) medicine importation requirements, radiation protection authorities, and approvals from applicable health regulatory bodies. Formal approval from an Institutional Review Board (IRB) or Human Research Ethics Committee (HREC) from the treating hospital must be also secured. If approved, the patient (or his or her guardian) must provide informed consent and consent to comply with the safety and monitoring requirements defined by Telix. The treating physician must also agree to comply with the safety and monitoring requirements. Compassionate use availability will immediately cease if, as a result of clinical trials, the product does not demonstrate a positive risk-benefit to patients.

For patients that meet Telix's criteria, treating physicians can make a request via compassion@TelixPharma.com.