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# Policy on Offering Compassionate Use and Early or Expanded Access to Investigational Medicines

Telix Pharmaceuticals Limited and its international operating subsidiaries ("Telix", "Company") is focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. Targeted radiation products and product candidates are typically administered to patients by specialist physicians, and we work closely with leading cancer centres worldwide to make a positive impact on patient care. To achieve this, we conduct clinical trials to assess the safety and efficacy of investigational medicines, which if proven, will enable us to obtain the necessary approvals from regulatory authorities to provide patients with broad access to these medicines. Typically, clinical trials are sponsored and controlled by the Company but in certain instances we also allow experienced physicians to run investigator-initiated trials.

In general, Telix believes that participating in clinical trials is the most appropriate way for patients to be treated with unlicensed and unproven medicines prior to regulatory approval and marketing authorisation. In some circumstances when this is not possible, patients with life-threatening conditions may seek special access to investigational medicines via a physician, outside of a formal clinical trial setting on a compassionate use basis. This is particularly the case for Telix's carbonic anhydrase IX (CAIX)-, prostate-specific membrane antigen (PSMA)-, and L-type amino acid transporter (LAT)- targeting programs for kidney cancer, prostate cancer, and glioblastoma, respectively. These early access programs are typically referred to as compassionate use, but can also be known as named patient request, magisterial prescribing, expanded access, early access and emergency use protocols.

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 Australian Therapeutic Goods Administration (TGA) or the United States 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, or early/expanded access 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 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 and as quickly as possible. Telix has ethical responsibilities to ensure the quality and integrity of clinical trials and to minimise the risk to both current research participants and future patients.

Telix also has ethical responsibilities for compassionate use or early/expanded access of our investigational medicines. We consider many factors when considering a request for compassionate use or early/ expanded access of an investigational medicine, such as the level of safety and efficacy supported by stringently obtained clinical data, the risk-benefit profile of the patient, the potential impact on the clinical development program, the phase of development, the experience of the requesting healthcare team with radiopharmaceuticals and probability and timing of regulatory approval. In addition, because we are developing radiopharmaceutical 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 or early/expanded access availability. At Telix, a compassionate use or early/expanded access 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 life-threatening.
2. There are no adequate alternative standard of care therapies or clinical trials (including Telix-sponsored) available to the patient.
3. Compassionate use is permitted under local laws and regulations in the country where the patient is receiving the proposed treatment.
4. Sufficient preliminary efficacy and safety data exist for the drug, enabling Telix to determine a risk-benefit analysis that is consistent with the establishment of a compassionate use or early/expanded access

program. Unless exceptional circumstance, this would likely not occur earlier than the commencement of Phase II studies and, depending on the clinical program.

5. Sufficient clinical data is available to identify an appropriate dose / dosing regimen.
6. 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.
7. Adequate supply exists to support both the ongoing clinical trials and approved compassionate use or early/expanded access, until and if an investigational medicine becomes commercially available.
8. The patient is not eligible or a potential candidate for one of the Telix-sponsored studies . Geographic limitations to participate in a trial would typically mean a patient is ineligible.
9. 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.
10. The request must be made by the patient's treating physician, unsolicited by Telix or any other individual or organisation.
11. The study centre or clinic has sufficient infrastructure and clinical support to ensure the safe administration of the product and adequate resources for patient monitoring and follow-up.

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 in accordance with local/national laws and regulations. Receipt of a request will be acknowledged promptly. All requests will be evaluated in a fair, unbiased manner. Patients with exceptional safety risks that have not been adequately studied would be excluded.

All compassionate use requests 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 the patient's guardian) must provide informed consent and consent to comply with the safety and monitoring requirements defined by Telix. The treating physician will also need to agree appropriate supply terms to establish context and respective roles and responsibilities between Telix and the responsible physician, including informed consent, ethics or other regulatory approvals, privacy laws, protocol (if applicable), and acknowledgement that treatment decision remains with physician for individual named patient requests. ).

Telix reserves the right to withdraw compassionate use supply or availability immediately 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:
Americas region: eap-americas@telixpharma.com
Asia Pacific region: eap-apac@telixpharma.com
Europe, Middle East and Africa region: eap-emea@telixpharma.com