Telix Pharmaceuticals Limited
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Policy on Offering Compassionate Use, Early Use or Expanded Access ("Managed 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 investigational medicines prior to regulatory approval and marketing authorisation. In some circumstances when this is not possible, patients with life-threatening conditions may seek Managed Access to investigational medicines via a physician outside of a formal clinical trial setting. These Managed Access programs are typically described as one of compassionate use under country-specific special access schemes, named patient request, magisterial prescribing, expanded access, early access or emergency use protocols.

A clinical development process involves controlled testing in humans to determine the safety and efficacy profile and this occurs with oversight from a regulatory body such as the Australian Therapeutic Goods Administration (TGA), the United States Food and Drug Administration (FDA), or European Union national competent authorities and ethics committees responsible for clinical trial authorisation in their member state. Managed Access may present significant risks for the patient and/or for the clinical development program. Patients access to an investigational medicine under Managed Access may bring potential safety risks or a clinically unverified expectation that the investigational medicine will provide benefit. For the clinical development program, safety and/or efficacy data and information emanating from a Managed Access case has the potential to undermine further clinical development and subsequently delay the approval of a new medicine.

Telix considers many factors when considering a request under its Managed Access scheme 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 Telix is 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 access availability.

At Telix, a single request under the Managed Access scheme can only be considered if the following conditions are met:

1. The patient's condition has potential to be serious or life-threatening and there are no adequate alternative treatment available to the patient.
2. The patient is ineligible for enrolment into or unable to access ongoing clinical trials.
3. The patient meets medical criteria determined by medical experts working on the development program.
4. Access and use is permitted under local laws and regulations in the country where the patient is receiving the proposed treatment.
5. Sufficient data exist for the drug enabling Telix to determine a risk-benefit analysis that is consistent with the establishment of the Managed Access program. This includes 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 Managed Access scheme until and if an investigational medicine becomes commercially available.
8. Managed 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 organisation.
10. 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.

Telix cannot make a guarantee that a Managed Access program will be available in respect of its investigational medicines, and, even if offered, Telix cannot make a guarantee that the investigational medicine will be available to a particular patient in a timely fashion.

Telix will consider Managed Access 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 Managed Access requests must 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.

If approved, and to the extent required by applicable laws, the treating physician will, prior to administering the investigational medicine made available under the scheme, obtain patient informed consent - properly disclosing, including without limitation, the potential risks and benefits of the investigational medicine and that the treatment is not approved for use in the patient's country. Telix and the treating physician will also need to agree appropriate supply terms to establish context and respective roles and responsibilities between Telix and the physician, including as relates to 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 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

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