Expanded Access Policy

Introduction

Candel Therapeutics believes that access to non-approved, investigational drugs is best given through a clinical trial. We understand that there may be circumstances under which a patient does not qualify for participation in a clinical trial. Under such circumstances Candel Therapeutics will carefully consider provision of access to investigational drugs to individual patients on a case-by-case basis.

Patients need to understand that treatment with an investigational drug on an individual basis outside of a clinical trial involves risks as the safety profile of investigational drugs is not fully established.

This document outlines the criteria under which Candel Therapeutics considers providing access to investigational drugs via an Expanded Access (Compassionate Use) Program under US FDA guidelines, the factors we take into consideration when evaluating the request and the procedures to request Expanded Access.

General Criteria:

Single-patient Expanded Access should only be considered if a patient is seriously ill and has exhausted approved treatment options and there is no option to participate in an ongoing clinical trial or soon to open clinical trial. Geographic limitations to participate in such a trial may not be a criterion to grant Expanded Access to an investigational drug.

Sufficient medical and scientific rationale needs to exist to suggest that the mechanism of action of the investigational drug may have a positive effect on the patient's disease burden, signs and symptoms, or prognosis.

The potential benefit to the patient seeking access to the investigational medicine must outweigh the potential risks to the patient receiving the investigational drug. This includes outcome of the disease itself.

Specific criteria related to the investigational drug

The investigational drug must have completed phase I clinical studies at a minimum to assure a preliminary basic understanding of and confidence in the investigational drug's safety profile and potential risks associated with treatment. The drug must be in active clinical development for its intended indication and early signs of efficacy in humans should have been reported prior to considering Expanded Access.

There may be underlying safety risks specific to a particular patient that may preclude him/her from access to the investigational drug.

Sufficient data must be available to have a basic understanding of the dosing frequency and strength for the patient requesting Expanded Access.

There may be only limited supply of an investigational product available. Access to an investigational medicine must not interfere with the completion of ongoing or planned clinical trials or otherwise compromise the development of the investigational drug.

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The treating physician must have access to a facility where the drug can be safely prepared for administration and safely administered to the patient via intratumoral injection. Candel Therapeutics does not provide materials required to safely administer the drug to the patient.

Candel Therapeutics in some cases does provide support for additional clinical testing, routine analyses, diagnostic or pathological testing to ensure the safety of the drug or to evaluate the benefit/risk ratio under compassionate use.

What patients should consider before requesting Expanded Access to an investigational drug

The physician and the patient need to understand that Expanded Access may only be possible/granted only for a certain time period, e.g. when there is only limited supply of an investigational drug available or additional trials open for which the patient would qualify. Once the investigational drug is approved by the regulatory authorities for the indication the patient is diagnosed with, Expanded Access will no longer be available.

New evidence from clinical trials may arise that could affect the safety profile or efficacy of an investigational drug or challenge the benefit/risk ratio under certain conditions. Under such circumstances, Candel Therapeutics reserves the right to withdraw its permission for compassionate use even if it was granted before.

How Candel Therapeutics evaluates Expanded Access requests

Candel Therapeutics takes every request for Expanded Access seriously and will decide on an individual basis and in close communication with the treating physician. Some guiding questions in the decision process include:

- Is the patient suffering from a serious or life-threatening illness?
- Is the patient eligible to enroll and able to participate in a clinical trial?
- Has the patient exhausted approved therapeutic options?
- Is the patient's medical diagnosis/status appropriate for the investigational treatment?
- Is the requested investigational treatment approved for any indication in the country concerned?
- Does the company have good confidence in the safety of the drug?
- Are clinical data available to suggest that the potential benefits for this patient outweigh the risks of the investigational treatment?
- Is the physician appropriately licensed and qualified?
- Is the company able to supply the investigational treatment?
- Will providing access on a single-patient basis negatively affect the company's ability to complete its clinical trials?

Candel Therapeutics always strives to make decisions as transparently as possible and does this in close communication with the treating physician and our internal team. The patient needs to understand that the final decision is with the company providing the drug. There may be circumstances under which Expanded Access **may not** be possible despite a positive opinion on all of the above criteria.

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Requesting access to investigational drugs via Expanded Access

General information

Requests for Expanded Access should be made by the patient's treating physician. Treating physicians are asked **not to** submit personal information (e.g. patient names) covered as protected health information in the initial request for Expanded Access.

The following information should be provided at the initial request:

- Contact details for key point of contact.
- The specific medical condition for which the physician is inquiring.
- Existing diagnostic information in support of the medical condition.
- The general medical status of the patient for whom Expanded Access is requested. Additional questions may be asked to further clarify eligibility.
- The place of residence of the patient and general ability to travel to the treatment center.
- A brief explanation by the treating physician that he/she is able to administer an investigational drug in an environment that ensures the safety of the patient.

The process

The process and the conditions for Expanded Access may differ from country to country. Below we describe the process for requesting Expanded Access under US FDA guidelines:

After Candel Therapeutics has positively decided on granting compassionate use access, in the United States, the FDA and an appropriate Institutional Review Board (IRB) must review and approve the use of the investigational drug to ensure that the patient or legal representative understand the potential risks associated with treatment using investigational drugs.

Once Candel Therapeutics and the IRB agree to the treatment under Expanded Access protocol, Candel Therapeutics will issue a Letter of Authorization to the treating physician, allowing the physician to cross-reference the IND for the investigational drug. The physician then requests permission to proceed from the FDA by submitting Form 3926. This can be done online @ https://www.fda.gov/about-fda/reports-manuals-forms/forms

Further information is found at https://www.fda.gov/news- events/expanded-access/expanded-access-how-submit-request-forms

Once the FDA grants permission, the physician informs Candel Therapeutics and provides appropriate documentation. Candel Therapeutics will then initiate the shipment of drug to the treatment center.

For additional information on compassionate use access or to submit requests, please contact:

info@candeltx.com

617.916.5445

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