



Expanded Access to Investigational Products for Individual Patients

Patients with a serious or life-threatening disease often want to know how they may receive access to investigational drugs that have not been approved by FDA or other regulatory agencies. When patients have exhausted all available medical options and are not eligible to enroll in clinical trials, companies such as Deciphera may consider requests from physicians to make an investigational drug available to their patients on an “expanded access” basis. Deciphera recognizes that these requests are complex and should be handled with great care. We have established the following policy to govern requests by physicians for expanded access to our investigational products for individual patients. At this time, Deciphera does not consider requests for expanded access of investigational drugs to a cohort or group of patients.

Deciphera will only consider granting a request made by a qualified physician for expanded access if the following conditions are met for both the patient and the investigational product:

Patient:

- The patient has a serious or immediately life-threatening disease or condition;
- The patient has exhausted all available therapies that have been approved for treatment of the disease or condition, and is no longer responsive to, or able to tolerate, these therapies;
- The patient is not eligible to participate in any ongoing clinical study of the investigational product or other similar investigational agents, or is otherwise unable to participate in the clinical studies; and
- There is sufficient evidence indicating that the potential benefits of expanded access outweigh the collective potential risks to the patient (and such risks are not unreasonable in the context of the disease or condition to be treated).

Investigational Product:

- The investigational product is in active clinical development in one or more clinical studies;
- There are sufficient clinical data about use of the investigational drug to identify an appropriate dosing regimen and suitable formulation;
- A sufficient supply of the investigational product exists and can reasonably accommodate the likely duration of treatment for the patient, taking into account the needs of clinical trials and other patients in treatment; and
- Expanded access to the investigational product will not compromise or interfere with clinical development of the product, including the initiation, conduct or completion of clinical trials.

If a request for expanded access appears to meet these criteria, the treating physician may contact Deciphera to submit a formal request via email at expandedaccess@deciphera.com. Deciphera will confirm receipt of a request submitted with complete medical documentation as quickly as possible, usually within 5 business days. Deciphera will evaluate the request and will promptly inform the requesting physician of Deciphera’s decision. Deciphera’s acceptance and



processing of an expanded access request does not guarantee that access to investigation product will be provided. We reserve the right to decline a request for expanded access if, for example, we believe that access may not be in the best interests of the patient, may adversely impact the development process of the investigational product, or may not satisfy the foregoing criteria or any other relevant medical condition for expanded access, as established by Deciphera.

In the event that Deciphera grants the request, the physician must comply with all applicable legal and regulatory requirements of the relevant jurisdiction and any additional requirements established by Deciphera, which may include safety reporting and protection of intellectual property. Any physician who receives an investigational product through expanded access must be properly licensed and fully qualified to administer the investigational product to the patient.

When applicable, this website will be updated with hyperlinks to the relevant expanded access records on www.clinicaltrials.gov after such records become active.

Deciphera Policy for Expanded Access
Version 2.0
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