Galapagos Policy

Expanded Access

Galapagos is focused on the development and commercialization of novel medicines that will improve people's lives. We encourage patients to participate in clinical trials whenever possible. These clinical trials are critical to developing the information (or data) needed to evaluate investigational products and seek their approval by health authorities, such as the United States Food and Drug Administration and the European Medicines Agency. In rare cases, patients are unable to participate in clinical trials and have exhausted all available treatment options. In these cases, Galapagos may consider providing an investigational product outside of a clinical trial, through a program called "expanded access." Expanded access is also often referred to as "compassionate use."

Galapagos will consider granting expanded access to an investigational product if the following conditions are met:

Patient:

- The patient has a serious or life-threatening disease or condition;
- The patient has exhausted all available therapies typically used to treat the disease or condition and is no longer responsive to, or able to tolerate, these therapies;
- There are no ongoing clinical trials of the investigational product or similar investigational products or planned clinical trials starting reasonably soon in which the patient is eligible, or the patient is otherwise unable to participate in one of these trials; and
- There is sufficient evidence of a potential benefit from the use of the investigational product and outweighs the potential risks, and those risks are not unreasonable in the context of the disease or condition being treated.

Investigational Product:

- The investigational product must be in active clinical development in one or more clinical studies;
- There are sufficient clinical data about use of the investigational product to identify an appropriate dosing regimen and suitable formulation;
- Providing expanded access will not interfere with clinical trials or other development efforts that could support the approval of the investigational product by a health authority, such as the U.S. Food and Drug Administration or the European Medicines Agency; and
- A sufficient supply of the investigational product is anticipated and may reasonably accommodate the likely duration of treatment for the patient, taking into account the needs of clinical trials and other patients in treatment.

How to Request Expanded Access:

Galapagos encourages patients to speak first with their physician about their eligibility to enroll in a clinical trial. If a treating physician believes expanded access may be the only option for the patient, the physician should contact Galapagos to make a formal request on behalf of the patient. The requesting physician must, if applicable, agree to obtain appropriate regulatory and ethics committee approvals and to comply with all other safety, monitoring, and patient consent

requirements defined by Galapagos and applicable regulations. Requests for expanded access may only be made by licensed physicians through the Galapagos Medical Affairs Department.

All individual patient expanded access requests submitted by a treating physician must include the following information:

- Date of request;
- Requesting physician's name, contact information, address (including country), and professional designation (i.e., MD) or qualifications;
- Name of the requested investigational product, along with physician's intended treatment plan, including therapeutic indication and expected duration of treatment; and
- Medical rationale for the request, including an explanation why alternative therapies cannot be used, why the patient does not qualify for an ongoing clinical trial or planned clinical trial starting reasonably soon or is otherwise unable to participate in one of these trials, and why the potential benefit from the use of the investigational product outweighs the potential risks and those risks are not unreasonable in the context of the disease or condition being treated.

Galapagos is committed to evaluating all requests for expanded access in a fair and equitable manner. Galapagos will acknowledge requests from licensed physicians as soon as possible, usually within 7 business days of receipt.

Questions about or requests for expanded access to Galapagos investigational products can be submitted to: medicalinfo@glpg.com.

In the event that Galapagos grants a request, the physician must comply with all applicable legal and regulatory requirements of the relevant jurisdiction and any additional requirements established by Galapagos, 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.

Galapagos reserves the right to revise this expanded access policy at any time. In addition, the posting of this policy does not guarantee access to any specific investigational product by any patient.