Transgene position statement on Early Access to Experimental Medicine

Why it matters?

TRANSGENE is an oncology-focused biotechnology company committed to delivering medicines that provide a better life for cancer patients.

Our development resources are focused on conducting scientific research that evaluates the safety and effectiveness of new medicines for patients with cancer who have the greatest clinical need. Before TRANSGENE's investigational medicines can be made broadly available, the health authorities around the world require that they are studied in clinical trials to determine if the medicines are safe and effective for prescription by physicians to patients, and that the benefits of their use outweigh the risks.

Since TRANSGENE's investigational medicinal products have not yet received regulatory approval, their safety and efficacy, with potential risks and benefits are not yet established. Throughout this clinical development process, the safety of patients taking our medicines is of the utmost importance; therefore participating in clinical trials is the best way for patients to access medicines prior to approval.

Where enrollment into a clinical trial is not an option, and where all currently available treatment options have been exhausted, patients with serious diseases or conditions may seek special access to investigational medicines. This access to investigational medicines is often referred to as expanded access, compassionate use, early access, special access, or by another name based on the country from which the request is being made.

TRANSGENE position statement and how to request early access?

TRANSGENE encourages patients to speak with their treating physicians about participating in a clinical trial, when possible. You can find additional information about TRANSGENE's ongoing clinical trials by accessing https://clinicaltrials.gov.

Consistent with the US FDA and other regulatory agencies' guidelines, Expanded access may be appropriate when all of the following apply:

- The patient has a serious disease or condition, or a patient's life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- The investigational medicine is currently being studied in clinical trials.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefits justify the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

As a general policy when assessing Expanded Access, TRANSGENE will not provide investigational medicines to patients until a dose and schedule has been established for the agent, preliminary data exists that the agent has some evidence of activity in a particular indication, and the investigational medicine is found to be safe as a result of a risk-benefit evaluation.

All requests for Expanded Access must come from a patient's treating physician and be submitted to clinical.trials@transgene.fr They will be evaluated and responded to on a case-by-case basis. Within such request, please include the following information:

- Name and Contact number of physician.
- Specific TRANSGENE's investigational medicinal product that is being requested.
- Do not include any information that may identify the patient.

TRANSGENE regularly monitors this mailbox and will use its best efforts to acknowledge each request within 5 business days after receipt.

If you are a patient and would consider a request for Expanded Access of a TRANSGENE's investigational product, please work directly with your treating physician.

As authorized by the 21st Century Cures Act, TRANSGENE may revise this Expanded Access Policy at any time. The posting of this policy by TRANSGENE shall not serve as a guarantee of access to any specific investigational medicine by any individual patient.