Expanded Access Policy

Expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational drug for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Kinnate BioPharma is currently limiting expanded access to the investigational drug KIN-3248 and offers expanded access to a limited number of patients who have participated in clinical trials of KIN-3248. To be granted this expanded access, additional criteria must be met:

- The patient to be treated must have no comparable or satisfactory alternative therapy is available to treat the disease or condition;
- Available information exists to believe the potential benefit of treatment outweighs the potential risk in the context of the disease or condition to be treated;
- Kinnate BioPharma has an adequate supply of the investigational drug;
- and providing the investigational drug will not interfere with ongoing clinical trial(s) or with the overall development program of KIN-3248.

Patients may be required to meet other important medical criteria established by Kinnate BioPharma.

Each request will be reviewed promptly by Kinnate BioPharma with every effort made to provide a response within a maximum of 10 working days once all required information has been received from the treating physician. This timeline may be changed by factors such as government health authority feedback and the responsible IRB review/approval.

If expanded access is granted, Kinnate BioPharma will provide the investigational drug free of charge to patients through their treating physician.

The Expanded Access Program

The Expanded Access Program is physician-sponsored, single-patient expanded access (EA) to KIN-3248. KIN-3248 is a novel, next-generation, irreversible small molecule pan-fibroblast growth factor receptor (FGFR) inhibitor for the treatment of patients with FGFR alteration-positive solid tumours. This program currently is only available through licensed physicians in the United States and is offered to those patients who previously participated in a KIN-3248 clinical trial in the U.S., to allow them to continue receiving KIN-3248 therapy. Kinnate Biopharma is the KIN-3248 drug provider and may provide possible assistance to the physicians for their EA applications.

Physician applicants are responsible for submitting required documents and obtaining all required approvals prior to requesting KIN-3248 drug supply. Kinnate Biopharma reserves the right to review, approve or reject EA applications based on case-by-case evaluation. The KIN-3248 drug supply is free of charge to treating physicians and patients after all approvals are granted. All patient care is the responsibility of the treating physician and the patient's own healthcare coverages.

A request must be submitted by the treating physician to richard@kinnate.com.

Kinnate Biopharma may revise this expanded access policy at any time, including termination of this EA program. Additionally, the posting of this policy does not serve as a guarantee of access to any specific investigational new drug by any individual patient and their physician. If you have any questions, please contact Kinnate Biopharma richard@kinnate.com.