

# Expanded Access Policy

Zydus Discovery DMCC (Zydus), a part of Zydus group with Cadila Healthcare Ltd. (India) as the ultimate parent company, is committed to developing promising new therapies to address the unmet medical needs of patients suffering from rare and seriously debilitating diseases.

Zydus believes the best way for patients to access medicines prior to approval is through participation in clinical trials, we are focused on enrolling and conducting the clinical trials necessary to gain regulatory approvals to make our medicines available broadly to patients as quickly as possible. In rare cases, when patients are unable to participate in clinical trials and have exhausted all available treatment options, Zydus may consider providing an investigational product to individual patients outside of a clinical trial through a program called “expanded access” or “compassionate use.”

Zydus will consider such special use outside of a clinical trial when all the following criteria are met:

- The patient has a serious or life-threatening illness or condition and is either no longer responsive to or no longer able to tolerate any available treatment option;
- The patient is not eligible or cannot participate in an ongoing or planned clinical trial;
- There is sufficient scientific evidence that the potential patient benefit justifies the potential risks of treatment;
- This Expanded Access use will not interfere with clinical trials or other development efforts that could support the approval of the investigational product by a health authority;
- The investigational drug is in active clinical development with sufficient data available to determine an appropriate dose and schedule for the patient's specific condition;
- There is sufficient supply to support both the ongoing clinical trials and prior approved expanded access requests;

Zydus is committed to evaluating all requests in a fair and equitable manner. All requests must be submitted by the patient's treating physician; Zydus may require more detailed information in order to fully evaluate a request. The requesting physician must agree to obtain appropriate regulatory and ethics committee approvals and comply with regulatory obligations, including obtaining patient informed consent, medical monitoring, safety reporting and data collection. Each request will be given careful consideration by Zydus whose decisions are final.

Physicians seeking pre-approval access for patients with no alternative treatment options should submit their requests to [deven.parmar@zydusdiscovery.ae](mailto:deven.parmar@zydusdiscovery.ae).

Zydus will acknowledge a request within 5 business days after receipt of the complete request. This request should indicate the date of request, the requesting physician contact information and a medical rationale for request including an explanation for why the patient cannot qualify for a clinical trial and why no alternative can be used.

Information about Zydus Discovery DMCC clinical trials can be found at <https://clinicaltrials.gov/>

This policy is not a guarantee of access to any Zydus investigational medicines.