



## ACCESS TO INVESTIGATIONAL MEDICINES PRIOR TO REGULATORY APPROVAL

Alkermes develops innovative new medicines designed to address unmet medical needs of patients in major therapeutic areas. We are focused on creating new medicines that address important, real world concerns of patients and their families. We currently have investigational treatments in clinical trials for a number of different diseases, as described in the Research and Development, Pipeline section of our website at <http://www.alkermes.com/research-and-development/pipeline>. Alkermes' goal is to efficiently bring safe and effective medicines to all appropriate patients by conducting rigorous clinical trials and obtaining marketing approval by regulatory authorities, including the U.S. Food and Drug Administration (FDA).

Prior to such approval, participation in one of our clinical trials is the optimal way for patients to gain access to our investigational medicines. However, we understand that some patients may not be able to participate in a clinical trial and may seek access to investigational treatments before they are approved.

If early data from clinical trials suggest that an investigational treatment can offer benefits for patients facing serious or life-threatening conditions, Alkermes may consider requests to provide access outside of a clinical trial. In reviewing any request, we will consider if:

- The patient to be treated has a serious or immediately life-threatening illness and there is no satisfactory alternative therapy
- There is preliminary clinical evidence of effectiveness and acceptable safety of the investigational treatment for that patient's condition
- The potential benefit of the investigational medicine to the patient is greater than the potential risk
- There is an adequate supply of the investigational medicine
- Providing the investigational medicine interferes with the timely completion of clinical trials that could lead to marketing approval and thereby could delay its availability to other patients.

Patients interested in obtaining access to an Alkermes investigational therapy must do so via their physician. Physicians should contact Alkermes' Medical Information Center at 1-888-235-8008 or [USMedInfo@alkermes.com](mailto:USMedInfo@alkermes.com). All requests will be carefully considered and a written or oral response will be provided to the treating physician within 2 weeks of receiving a request.