Compassionate Use Policy

In cases where a patient has a serious or life-threatening disease or condition and has exhausted the standard of care and alternative treatment options, there may be promising, experimental therapies available through participation in a clinical trial. However, if all of these options have been exhausted, and in the event that Taro is developing a medicine that has shown promise for treating a serious or immediately life-threatening disease or condition, the patient's treating physician may apply to Taro for *compassionate use access* to the investigational medicine.

Requests should be submitted via email to compassionate.use@taro.com by the patient's treating physician and certify as to:

- the serious or immediately life-threatening disease or condition that the patient has;
- the patient having exhausted all of the standard of care treatments, as well as the relevant alternative/recognized treatments and supporting details;
- the patient being unable to enroll in (or ineligible for) ongoing clinical studies of the investigational medicine;
- the basis for the treating physician's recommendation for compassionate use access to the investigational medicine;
- his/her agreement to oversee the use of the investigational medicine and that he/she will cooperate with Taro with respect to any requests for additional information about the use of the investigational medicine and/or regulatory agencies with respect to such requests;
- his/her willingness to file the necessary regulatory documents and manage safety reporting to the local regulatory agency and to Taro;
- the expected quantity of the investigational medicine and treatment timeframe.

In reviewing a request, we will consider the following factors:

- whether the relevant, recognized treatment options have been exhausted;
- whether sufficient clinical data are available to determine the appropriate dose;
- the potential benefit to the patient and risk, and the scientific or medical rationale indicating that the patient may benefit from the investigational medicine;
- the available supply of the investigational product.

Upon receipt of the above request and documentation, we will respond to the request as quickly as possible, within 7 calendar days.

For additional information about clinical trials involving our drugs, please refer to the information available at https://clinicaltrials.gov.