

EXPANDED ACCESS PROGRAM

Signpath Pharma



Sometimes called “compassionate use”, expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

When seeking expanded access to an investigational medical product, it is critical that the patient and his/her licensed physician consider all possible risks. Investigational medical products have not yet been approved or cleared by the FDA and FDA has not found these products to be safe and effective for their specific use. Furthermore, the investigational medical product may, or may not, be effective in the treatment of the condition, and use of the product may cause unexpected serious side effects.

Whenever possible, an investigational medical product should be used as part of a clinical trial. However, if patient enrollment is not possible (e.g., patient ineligibility, lack of ongoing clinical trials) or enrollment in a clinical trial is not feasible (e.g., distance to a trial precludes access), expanded access offers a possible route for gaining access to an investigational medical product.

Signpath Pharma is committed to developing category defining drugs that address the unmet medical needs of patients suffering from rare and seriously debilitating diseases.

We currently have clinical and late-stage investigational medicines in our product pipeline for the treatment of cancer, cardiac arrhythmia, and cardiomyopathy.

Our goal is to provide access to our medicines at the appropriate time and in a manner that is most beneficial to the relevant patient population. We believe enrollment in our ongoing clinical trials is the safest and most effective way of achieving this goal.

We do recognize that some patients will not be eligible for our clinical trials and may wish to access our products through expanded access. However, at this time, we do not have the resources available to offer expanded access use of our investigational medicines.

We encourage all patients and physicians who are interested in accessing our investigational medicines to visit the clinical trial section of our website to find out about enrolling.

Signpath Pharma may revise this expanded access policy at any time, and we reserve the right to offer expanded access in exceptional circumstances. Additionally, the posting of this policy by Signpath Pharma does not serve as a guarantee of access to any specific investigational new drug by any individual patient.

If you have any questions regarding Expanded Access, please reach out to Kai Larson - klarson@signpathpharma.com.