Theravance Expanded Access Policy

Theravance Biopharma, Inc.'s ("Theravance") overarching purpose and goal as a biopharmaceutical company is to deliver Medicines that Make a Difference® in peoples' lives.

Theravance conducts clinical trials to assess the safety and efficacy of investigational products. Regulatory agencies such as the U.S. Food and Drug Administration ("FDA") must review and approve investigational products before they can be made generally available to the public. We believe that participation in one of our clinical trials is the most appropriate way to access our investigational products. Theravance encourages patients to speak with their treating physicians and when possible, to participate in clinical trials. For more information on Theravance clinical trials that may be recruiting, search "Theravance" at www.clinicaltrials.gov.

Regulatory agencies, such as the FDA, may approve programs that grant a patient access to an investigational product if the patient has a serious or immediately life-threatening disease, the patient has exhausted all available treatment options, the patient is unable to enroll in a clinical trial, and the manufacturer of the investigational product agrees to make it available to the patient. Such individual use of an unapproved investigational product is often called "expanded access" or "compassionate use." The terminology used can vary from country to country and is dependent on the way that the that investigational product is accessed.

It's important to remember that investigational products have not yet received regulatory approval; therefore, their potential risks and benefits are not yet established. Patients and their physicians should consider all possible benefits and risks when seeking expanded access to an investigational product.

If a patient is interested in gaining access to a Theravance investigational product, they should consult with their treating physician. To request expanded access, the treating physician must apply on behalf of their patient and provide all necessary information to demonstrate eligibility, in accordance with our expanded access policy outlined below.

Our Policy

Theravance will consider several criteria, when evaluating individual requests for access to our investigational products, consistent with the FDA and other regulatory agencies' guidelines.

Theravance will consider granting individual patient access to its investigational products only if all of the following criteria are met:

- The patient has a serious or life-threatening disease or condition;
- No comparable or alternative therapy (such as approved products or enrolling clinical trials) is available to treat the disease or condition;
- The patient is ineligible for or unable to access any ongoing clinical trials for the investigational product;
- There is compelling evidence to believe the potential benefit of use of the investigational product outweighs the potential risk in the context of the disease or condition to be treated;
- There is sufficient clinical data to identify an appropriate dose;

- Adequate supply of the investigational product is available to support all ongoing clinical studies in addition to the requested expanded access use;
- There is a regulatory mechanism in the country from where the request originated to support the approval of the expanded access request and importation of the investigational product;
- The investigational product is either (1) in active development by Theravance, including active or planned clinical trials or (2) under review for approval by a regulatory authority;
- Providing the investigational product will not interfere with ongoing clinical trial(s) that could support the development or marketing approval of the investigational product for the treatment indication; and
- The treating physician is willing to enter into an expanded access agreement with Theravance.

Theravance will evaluate and respond to each expanded access request that it receives on a case-by-case basis, and all final eligibility determinations shall be made by Theravance in its sole discretion. Please note that submission of an expanded access request does not guarantee that access to the investigational product will be provided.

If expanded access is granted, the patient's physician will be responsible for and must oversee all aspects relating to the use of the investigational product under expanded access including, but not limited to, regulatory compliance, informed consent, ethics committee (EC) / institutional review board (IRB) approval, patient treatment, adverse event management and reporting.

Any approval of expanded access to an investigational product must always comply with applicable country-specific laws and regulations, including importation requirements, approvals from applicable regulatory agencies and notification or approval by an EC/IRB, as deemed appropriate per institutional policies and local laws.

Procedure for Requesting Individual Patient Access

Requests for individual patient access to use of a Theravance investigational product must be initiated by a treating physician of a specific patient. Physicians should send expanded access requests to expandedaccess@theravance.com. Please include the following information with your request:

- Physician name
- Physician phone number and email
- Institution name
- Physician address, including country
- Name of investigational product requested
- Patient's age (to comply with privacy laws, **do NOT include any patient identifiers such as name, initials, date of birth, address or contact details**)
- Disease/condition to be treated
- Proposed duration of use of the investigational product
- Rationale for request, including details regarding whether the patient meets the eligibility criteria listed above.

Requests should include sufficient supporting detail to enable Theravance to evaluate the request and the physician's willingness and ability to support the expanded access use in accordance with this policy.

Anticipated Timing

If a physician submits an expanded access request to Theravance in accordance with the procedure set forth above, Theravance will endeavor to acknowledge receipt of the request within ten (10) business days.

Cessation of Expanded Access

Theravance may consider ceasing expanding access for various reasons, including but not limited to:

- Commercial availability of the medicine for a particular need or condition, at which point it would be more broadly available to these patients in need;
- A negative regulatory decision, or the company's decision to end its development program for a particular investigational product in a particular disease or condition. In this instance, patients on expanded access treatment at the time of such a decision may be allowed to continue to access therapy until disease progression;
- New information becomes available about the activity or safety of a medicine that could substantially change its benefit/risk profile;
- Limited product supply or other manufacturing issues.

Expanded Access Records

The company does not currently have any expanded access programs, however, this policy will be updated with a hyperlink to the relevant expanded access record(s) on https://clinicaltrials.gov after any such records become active.

Resources

The US Food and Drug Administration has provided information about expanded access for patients, physicians, and industry. In Europe, the European Medicines Agency has also provided recommendations. Other global health authorities may also have specific recommendations for expanded access programs which may allow some patients access to investigational products outside of a clinical trial. Theravance is committed to complying with all applicable laws, regulations, and requirements in the applicable region(s).

The posting of this policy by Theravance shall not serve as a guarantee of access to any specific investigational drug by any individual patient. As authorized by the 21st Century Cures Act, Theravance may revise this expanded access policy at any time and for any reason. All expanded access requests shall be considered by Theravance in its sole discretion.