

Constellation Pharmaceuticals, Inc.
Expanded Access Policy

Updated August 2018

1. Clinical Trials

Constellation Pharmaceuticals, Inc. (Constellation) believes that participating in clinical trials is the best way for patients to access Constellation's investigational medicines prior to approval. To participate in a trial, you must meet certain criteria. For those who meet the criteria to join a clinical trial, participation offers the chance to contribute to medical research that may benefit many others. Participation in a clinical trial comes with certain risks; that is why "informed consent" is a required step in the process of enrolling.

Information regarding Constellation's pipeline of investigational medicinal products can be found at www.constellationpharma.com/our-programs/#pipeline. Information regarding specific Constellation clinical studies can be found at <https://clinicaltrials.gov>.

2. Compassionate or Expanded Access

In some circumstances when participation in an ongoing clinical trial is not possible, patients with life-threatening diseases may seek and regulators may grant special access to investigational medicines outside of a clinical trial setting. These situations are typically referred to as "compassionate use" or "expanded access" cases.

It's important to remember that investigational drugs have not yet received regulatory approval; therefore, their potential risks and benefits are not yet established. Doctors and patients should consider all possible benefits and risks when seeking compassionate access to an unapproved product.

Constellation will review requests for compassionate/expanded access of its investigational products under the following criteria:

- A strong biological rationale or clinical data that support the possibility that the potential benefits of administration of the investigational medicinal product to the patient for that serious/life-threatening condition could outweigh the potential risks.
- The patient's physician has determined that treating the patient with the investigational product is in the patient's best interests.
- The investigational medicinal product will be administered in accordance with applicable laws and regulatory requirements of the country where the patient is treated, including importation requirements.
- The patient is not eligible or able to participate in a clinical trial or similar sponsored access program and no therapeutic alternative is available.
- Providing the investigational medicine should not interfere with the timely completion of clinical trials that could lead to marketing approval and thereby delay its availability to other patients.

All requests will be evaluated in a fair, unbiased manner. If approved, the patient (or his or her guardian) must provide informed consent and consent to comply with the safety and monitoring requirements defined by Constellation. The treating physician must also agree to comply with the safety and monitoring requirements. Compassionate use will cease being made available if ongoing clinical

trials do not demonstrate a positive risk benefit to patients.

For patients that meet Constellation's criteria, treating physicians can make a request to Constellation at expandedaccess@constellationpharma.com . Please submit sufficient supporting detail with your request to enable Constellation to evaluate the patient's circumstances based on the criteria listed in this policy, including:

- The date of the request
- Requesting physician's name, contact information, address (including country), and professional designation (i.e., MD) or qualifications
- Name of the requested investigational medicinal product along with physician's intended treatment plan, including therapeutic indication and expected duration of treatment
- Medical rationale for request including an explanation for why alternative therapy cannot be used, why the patient does not qualify for a clinical trial, and why use of the investigational drug is in the patient's best interest

Receipt of a request will usually be acknowledged within two weeks of receiving the request.