Summary of Savara Inc.'s US Expanded Access Policy

V1 May 2019

Expanded access generally refers to access to, and the use of, an investigational medical product (drug, biologic, or medical device) for patients with an immediately life-threatening condition or serious disease or condition outside of a clinical trial when no comparable or satisfactory alternative therapy options are available.

Investigational drugs are drugs that are not approved by regulatory agencies like the United States Food and Drug Administration (FDA). Clinical trials are used to test investigational drugs to establish their safety and efficacy before they are approved. Approval by regulatory authorities like the FDA is the only way to make treatments broadly available to the patient population.

Savara believes that participation in clinical trials is the preferred way for patients to access an investigational drug because these trials generate the efficacy and safety data needed to determine whether the investigational drug should be approved. Additional information about Savara's ongoing clinical trials of its investigational products can be found at: clinicaltrials.gov.

The following is a summary of Savara's expanded access policy for the United States. This policy does not serve as a guarantee of access to any Savara investigational product by any individual patient. This policy is subject to change from time to time, and Savara reserves the right to terminate or modify it at any time.

Procedure for Submitting Requests to Savara

Savara will consider expanded access requests from treating physicians subject to US laws and regulations.

All requests should be submitted via e-mail to EAP.US@savarapharma.com. Receipt of a request will be acknowledged within 5 business days.

Process for Review of Requests

Savara is committed to a fair and impartial evaluation of each request for access to its investigational products. Therefore, all decisions are based solely on clinical circumstances and are guided by the criteria outlined below. Patients will be referred to ongoing clinical trials as the primary way to access investigational products.

When evaluating requests for expanded access, Savara considers *all* of the following criteria:

1. The patient for whom expanded access is requested suffers from a disease or condition that is serious or life-threatening.
2. There are no comparable or satisfactory alternative therapies or clinical trials available.
3. Sufficient preliminary efficacy and safety data exist to support an assessment that the benefit for the patient outweighs the potential risks and that the potential risks are not unreasonable in the context of the disease or condition being treated.
4. Sufficient clinical data are available to identify an appropriate dose (amount and frequency) of the investigational drug.
5. There is adequate drug supply to support the ongoing and necessary clinical trials as well as to support approved expanded access in a sustainable and equitable manner, until and if product becomes commercially available.
6. The patient is not eligible to participate in any ongoing clinical trials of the investigational drug.
7. Expanded access will not adversely affect the clinical development program, in particular, the initiation, conduct, or completion of the clinical trials that are required for regulatory approval.
8. The unsolicited request is made by a U.S. qualified and licensed physician who will take primary responsibility for supervising use of the investigational product from Savara and will comply with all applicable FDA regulatory requirements associated with treatment and use of an investigational product.
9. All required regulatory and institutional approvals have been obtained. The patient must provide written informed consent.

Requests for expanded access will be individually reviewed in accordance with these criteria. Savara is committed to evaluating all requests for expanded access in a fair and equitable manner. All requests will be evaluated by medical professionals and decisions will be based on available scientific evidence at the time of the request.

Questions regarding Savara ongoing US expanded access program(s) can be forwarded to: EAP.US@savarapharma.com

This policy is not applicable to countries outside the US. If you have questions on expanded access in a non-US country, please submit your request to info@savarapharma.com.