# Position on Expanded Access to Investigational Medicines

## Background

Astellas is committed to making our medicines available to patients in the most efficient manner to address their unmet medical needs. The general approach is through the conduct of clinical trials and subsequent registration and commercialization of our products. However, Astellas recognizes that patients with serious or life-threatening diseases may have exhausted all of their available treatment options, may not qualify for a clinical trial and may seek access to investigational medicines.

## Our Position

Astellas commits to establishing expanded access plans for investigational medicines and patients that satisfy the following conditions:

1. The disease or condition being studied is serious or life-threatening
2. The patient has exhausted all available treatment options
3. The provision of expanded access does not delay, interfere or compromise the completion of the clinical trial process and registration of the medicine
4. The medicine is in active clinical development and not available on the commercial market
5. Patient is ineligible for clinical trials
6. There is sufficiently robust preliminary safety and efficacy data including dosing information
7. The potential benefit to the patient outweighs the risks
8. The patient's physician, the institutional review board/ethics committee and regulatory authority have authorized the provision of the investigational drug

The decision to provide the medicine to a patient will be made by Astellas based on a fair and impartial evaluation of the requests that meet the conditions described above. This decision will be made in a timely manner to be responsive to the patient's needs but with appropriate consultation and discussions with Astellas medical and clinical teams, the patient's physician, regulatory authorities and outside experts. As a general guideline, a response will be provided to expanded access requests within 7 days of receipt if not sooner.

This procedure will be implemented in compliance with local regulations in the country where expanded access is requested. Expanded Access programs will be targeted for countries where active clinical development is underway and registration of the medicine is planned. Generally

once a medicine is approved and on the market in a country, the expanded access program will no longer be available.

Astellas provides information on Expanded Access programs appropriately.* Patients should speak with their physicians in regards to seeking eligibility and access to the Astellas Expanded Access Programs.

* Information on Expanded Access protocols can be found at *Astellas EAPs*. Further information on Expanded Access programs at Astellas can be provided through the following contact.
Contact Information for physicians:

- E-mail: expanded.access@astellas.com
- TEL for physicians in the US: 800-727-7003
- Physicians outside the US: Call local Astellas office (http://www.astellas.com/worldwide.html)

**References**


- Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results by PhRMA (June, 2015)
- BIO Principles on Expanded Access to Investigational, Unapproved Medicines (April, 2015)
- A vision towards a life sciences strategy for Europe by EFPIA (2014)