AstraZeneca's Position on Early & Post-Trial Access to Medicines

March 2024

AstraZeneca

Commitment to Patients

Our purpose at AstraZeneca is to push the boundaries of science to deliver life-changing medicines to patients across our therapy areas of oncology (cancer), biopharmaceuticals (focusing on cardiovascular, renal, and metabolic conditions, respiratory conditions, immunology and neuroscience) and rare diseases.

Our work is marked by a commitment to the highest standards of preclinical and clinical research, and an acute sense of urgency. As such, prior to commercial availability of our medicines, we prioritise access to our medicinal products through participation in a clinical trial. AstraZeneca has ongoing clinical trials across our therapy areas, which are listed in the Pipeline section of our website. For a list of clinical trials currently recruiting patients, please visit www.astrazenecaclinicaltrials.com.

We understand that there are some circumstances where patients around the world with serious or life-threatening conditions, and for whom other treatment options are unavailable, may seek access to a medicinal product before it is approved in their country. For example, if there is no suitable clinical trial (referred to as 'early access') or if the patient needs to continue taking a medicinal product after their participation in a clinical trial has finished (referred to as 'post-trial access'). In such circumstances, we systematically evaluate and, when possible, plan for other appropriate access routes throughout the drug development process, in line with local laws and regulations.

Criteria for Consideration

- All access requests must come from a patient's treating physician. Patients who feel they need access to an AstraZeneca medicinal product should therefore begin by talking to their doctor.
- AstraZeneca will consider granting access when the following conditions are met:
- The access programme would not compromise the clinical development or regulatory approval of the medicinal product.
- The patient is unable to participate in a clinical trial.
- The patient has a serious or life-threatening disease or condition.
- The patient has exhausted or cannot be satisfactorily treated with any other currently available therapeutic options.
- The benefit outweighs the risk to the patient, based on sufficient clinical data.
- The patient is able to travel to an appropriate facility to receive the medicinal product and is under the care of a physician licensed and qualified to administer the medicinal product.
- The physician agrees in writing to comply with AstraZeneca's requirements related to patient confidentiality and data privacy, medical criteria, adverse event/safety reporting, treatment monitoring, medicine supply handling and use, and protection of AstraZeneca's proprietary information and/or intellectual property and agrees to perform such duties on a continued basis while the patient is receiving the medicinal product.
- Access can be provided in a manner that is compliant with applicable local laws and regulations.
- For Rare Disease Early Access requests please find criteria for consideration here: https://alexion.com/our-commitment/managed-access-programs.

Evaluation of Access Requests

AstraZeneca will acknowledge receipt of all requests immediately, via an automatic reply. Requests are then reviewed on a fair and impartial basis, depending on the availability of the medicinal product in question and an assessment of the criteria for consideration (see above). The decision to provide access will be based on clinical and scientific evidence relating to the medicinal product, the patient's eligibility for access, and the likelihood of the requested medicinal product meeting the patient's unmet medical need. Decisions will be made in consultation with the patient's treating physician and in line with local laws and regulations.

How to Request Access

AstraZeneca has privacy and security policies in place to protect information that is submitted. However, requests should not include any patient-identifying information.

Access requests can be submitted by physicians via the following methods:

- By contacting the AstraZeneca Medical Affairs team in the local country
  - USA: Medical Information Call Centre: 1800-236-9933
  - Outside of the USA: an overview of websites of the individual countries where AstraZeneca has subsidiaries can be found at Local AstraZeneca Affiliates
- Online, via the Early Access Request Platform (registration is required)

Contact Us

General enquiries related to access may be submitted to EarlyAccess@AstraZeneca.com