Early Access to Medicines Scheme – Treatment protocol – Information on the pharmacovigilance system and requirements for reporting safety data

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed and 'off label' medicines to UK patients that have a high unmet clinical need. The medicinal products included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. In some cases the safety profile of the EAMS medicine may not yet be fully established and it is therefore particularly important that any harmful or unintended responses to EAMS medicines are reported. More information about the scheme can be found here:
https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

Healthcare professionals should enrol any patients receiving EAMS medicines in the registry which the pharmaceutical company will have in place to enable systematic collection of information on adverse events. Suspected adverse drug reactions (ADRs) for any patients, particularly those not enrolled in a study (or registry), can be reported directly to the MHRA via the Yellow card scheme at www.mhra.gov.uk/yellowcard.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, outcome and results of any test results or investigations. Alternatively, healthcare professionals can report ADRs which occur in patients not enrolled in any study (or registry) directly to the pharmaceutical company who manufactures the EAMS medicine.

The information below is intended for healthcare professionals and is provided by the pharmaceutical company that manufactures the medicine. The description below summarises the requirements for clinical monitoring and reporting of adverse events with medicines used under the scheme. Prescribing doctors should also consult the relevant detailed information provided by the company.

Osimertinib (AZD9291) 40 mg film-coated tablets
Osimertinib (AZD9291) 80 mg film-coated tablets

Information on the Pharmacovigilance system:

When a prescribing physician requests access for a patient into EAMS, they will receive a set of programme materials from the company which will include detailed information on the collection and reporting of adverse events (AEs) and all the necessary forms and contact details.

All Healthcare Professionals involved in EAMS will be instructed to report to the company all serious adverse events (SAEs), all drug-related non-serious adverse events, events of special interest, any pregnancies and overdoses as specified in the relevant documentation in the physicians pack. The Physician Pack includes:

- Prescribing Guidance for physician
- Information for the patient
- Patient Access Form
- Patient Resupply Form
- Safety Reporting Treating Physician Training

- Details on the use of the online portal
- Patient alert card

All Healthcare Professionals involved in EAMS will be instructed to report to the company all serious adverse events (SAEs), events of special interest, pregnancies and overdoses within 24 hours and all drug-related non-serious adverse events (NSAEs) within 5 days.

Certain AEs may require additional information and further details will be requested from physicians as required. In addition to this routine follow-up, AstraZeneca will proactively follow-up with all physicians on a 2-weekly basis to ascertain if any enrolled patients have experienced AEs. Physicians will be reminded to report any observed AEs in line with the requirements set out in the physician pack. In addition, they will be requested to respond even if no AEs have been observed.

Training for Healthcare Professionals (HCPs)

All prescribing physicians involved with the management of the EAMS will receive training on reporting of AEs and the use of the online portal.

The training pays particular attention to recognising, managing and reporting AEs.

The HCP receives and is asked to provide a Patient Alert Card to each patient at initiation of their treatment (see below).

Additional information:

This provision of osimertinib (AZD9291) through EAMS is designed to provide early access to this medicine to patients with locally advanced or metastatic EGFRm Non-Small Cell Lung Cancer, not amenable to curative surgery or radiotherapy, with confirmation of the presence of the T790M mutation where there is a clear unmet medical need, prior to licensing of this product in the UK.

The prescribing physicians will be requested to provide anonymised patient data for each patient enrolled in EAMS prior to start of treatment. This includes:

- Patient age
- Patient gender
- Disease status and confirmation of T790M mutation presence.
- Previous treatment and current medications
- Underlying co-morbidities

The activities below are additional to spontaneous reporting and are designed to encourage prescribers to report AEs:

- Collection of drug-related non-serious adverse events, pre-specified events of special interest and serious adverse events.
- Provision of AE reporting instructions
- Reminding of physicians to report AEs with each resupply of drug
- Provision of training to sites in pharmacovigilance obligations and reporting process
- Provision of a patient alert card
- Proactive 2-weekly AE follow-up with all physicians with enrolled EAMS patients

Periodic Reporting

AstraZeneca will submit a periodic report every 3 months (whilst the EAMS is ongoing) to the MHRA summarizing any safety findings from the EAMS.

Patient Alert Card

Before treatment starts, all patients will have the scheme explained to them by the prescribing physician and will be given a Patient Alert Card. The Patient Alert Card is a credit-card sized card and must be carried by the patient at all times. This card summarises the most important side effect for which patients need to seek assistance should they occur and carries the details of their own physician who will be managing their treatment. In addition the card alerts any other healthcare professional that may treat the patient that they are receiving osimertinib through an early access scheme. The pharmaceutical company contact details are also included.

Contact details:

astrazenecaUKMCdrugsafety@astrazeneca.com

Telephone number for AstraZeneca Medical Information: 0800 783 0033