Medicines & Healthcare products Regulatory Agency

MHRA

EAMS 04425/0002 isatuximab

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: http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

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.

Information on the Pharmacovigilance system:

When a treating physician requests entry into the EAMS scheme they will receive an electronic physician pack. The pack will include information on reporting of adverse events (AEs) and all the necessary forms and contact details (see below).

The physician pack will contain a copy of all documents being used in EAMS:
- Instructions on entering patients into EAMS
- Patient enrolment form
- Treatment Protocol for Health Care Professional (HCP)
- Treatment Protocol for Patients (Information for patients)
- Patient Alert Card
- Reference slides describing the Important Identified Risks
- Individual Safety Information Form (for HCPs)
- Patient Consent Form

Active Pharmacovigilance:
All HCPs, (physicians, pharmacists and nurses) involved with the EAMS programme will be directed to report the following (PV Data):
- Any adverse events (AEs) regardless of seriousness (Please note this includes any AEs listed in the treatment protocol),
- Use in pregnancy or lactation
- Lack of efficacy
- Overdose
- Drug misuse or abuse
- Medication errors
- Off label use
- Occupational exposure
- Abnormal laboratory findings
- Unintended beneficial effects
- Transmission of infectious agents

Within 1 working day of awareness using the 'Isatuximab EAMS adverse event reporting form' included in the physician's pack.

A unique identifier will be generated by the Sanofi Medical team once an individual patient is accepted in to the EAMS scheme. This unique identifier will take the format ISA-XX-NNN where ISA stands for Isatuximab, XX is a two letter centre code and NNN is a sequential patient number for the number of patients enrolled within the whole EAMS programme. The unique identifier will be used to track and deliver stock to/ from the hospital pharmacy and will also be used for monitoring safety information. This number will remain in a database of patients entered into EAMS. In the event that a patient enrols in EAMS but does not receive treatment, the unique identifier will not be reused.

The physicians will be trained by the Sanofi medical team to report all safety information identified to the Sanofi Pharmacovigilance team using the Isatuximab EAMS adverse event reporting form. Physicians will also be trained on the important identified risks associated with isatuximab treatment, a slide deck will be included in the physician's pack for reference.

Proactive Pharmacovigilance Measures:

The Sanofi Pharmacovigilance team will request that each site notifies the pharmacovigilance department of the date of each patient's first infusion.

In addition each site will be requested to return an Isatuximab EAMS adverse event reporting form at the end of each treatment cycle. If no pharmacovigilance data was experienced by the patient the site will be asked to return the form indicating this.

The Pharmacovigilance team will actively monitor to ensure that the appropriate number of forms are returned for each patient based on the date of the patients first infusion. The pharmacovigilance team will contact the sites to request any EAMS adverse event reporting forms if the forms are not returned at the appropriate points within the patients treatment cycle.

Pharmacovigilance data will be captured throughout the scheme until the end of EAMS for a particular patient. For patients who withdraw from the EAMS every effort will be made to obtain follow information for up to 3 months after withdrawal.

In accordance with Sanofi pharmacovigilance procedures and in alignment with GVP module VI guidance, all safety information received by the Sanofi pharmacovigilance team will be validated, assessed for causality and reported via Eudravigilance database to the appropriate health authorities.

If appropriate all reports will be followed-up as necessary to obtain supplementary detailed information significant for the scientific evaluation of the cases. The data management of all safety information will be in accordance with Sanofi pharmacovigilance procedures and the guidance listed in section VI. B4 of GVP module VI.

Sanofi will produce a 3 monthly periodic report of all AE reports received via the EAMS scheme, the first data lock point (DLP) will be 3 months from the date of scientific opinion. Submission of the report will be 1 month post DLP. The 3 monthly reports will continue until the end of the EAMS scheme with a final report to be submitted 1 month after the expiry of the EAMS scientific opinion.

Training for Healthcare Professionals (HCPs)

All HCPs involved with the management of the EAMS will receive training from Sanofi in addition to the information they receive in the physician pack upon set up.

For the main physician at each site (and any other recommended healthcare professionals), the Sanofi medical team will provide training prior to supply of isatuximab. This will include a presentation of key clinical data, product information, safety information reporting, important identified risks associated with isatuximab treatment and logistics of the EAMS.

As part of this training, the treating physician will be asked to provide a Patient Alert Card to each patient at initiation of their treatment (see below).

Patient Alert Card:

Before treatment starts, all patients will have the scheme explained to them by their treating physician and will be given a Patient Alert Card.

This is a wallet-sized card and patients must be instructed to carry it with them at all times. It serves to inform any other healthcare professionals that may treat the patient that they are receiving isatuximab through an early access scheme, and provides information about their treating physician, out of hours contact details and the Company’s contact information. The card also provides details of the important identified risks associated with isatuximab treatment.

Additional information:

This provision of isatuximab through EAMS, in combination with pomalidomide and dexamethasone, is designed to provide early access, for the treatment of adult patients with relapsed and refractory multiple myeloma only if they have received 3 previous lines of therapies (that have included lenalidomide and a proteasome inhibitor) and have demonstrated disease progression on the last therapy.

The treating physician will be requested to provide information for each patient receiving isatuximab through EAMS. Eligibility criteria including certain diagnostic, demographic, performance status and prior treatment information must be documented and shared with Sanofi in order to ensure eligibility to the scheme.

Contact details:

EAMS Programme:

To request access to EAMs: https://www.sanofi.com/en/compassionate-use/ Contact email for the EAMS programme: GB-eams-oncology@sanofi.com

Medical Information:
Telephone Contact: Sanofi Medical Information number (including out of hours):
Tel: 0845 372 7101
Contact email for Sanofi Medical Information: uk-medicalinformation@sanofi.com

Pharmacovigilance:
Contact details for reporting AEs: 0800 0902314
Email Address for reporting AEs: uk-drugsafety@sanofi.com
Facsimile Transmission for reporting AEs: 08004716122