Medicines & Healthcare products Regulatory Agency

MHRA

## 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

Healthcare professionals should enroll 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.

## EAMS Indication

Polatuzumab vedotin in combination with bendamustine and rituximab is indicated for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in adult patients who are not eligible for hematopoietic stem cell transplant.

## Information on the Pharmacovigilance system

A prescribing clinician may request entry of their patients into the Early Access to Medicines Scheme (EAMS) by completing and submitting an Initial Application and Drug Supply Request Form. Upon review of the individual request and fulfilment of the eligibility criteria, Roche will provide EAMS materials which will include information on the collection and reporting of adverse events.

All Healthcare Professionals (HCPs) involved in the care of patients on EAMS will be instructed to report all adverse events (AE), whether or not there is an associated AE within one business day of awareness as specified in the Safety Reporting Cover Letter in the Physician pack.

The AE reporting form is also included in the physician pack. HCP's can request additional copies of this AE reporting form by sending email to welwyn.contact_line_uk_dsc@roche.com.
Additional follow-up may be requested on all reports received to obtain further information.

All AEs reported will be entered into the Roche safety database and will be linked to the patient by the specific EAMS protocol number and unique patient number.

## Training for Healthcare Professionals (HCPs)

In addition to the Physician Pack, comprehensive AE training will be provided to all relevant HCPs prior to commencement of patient treatment, focusing on recognising, managing and reporting AEs during the scheme. Equally, the HCPs obligation to keep their patients fully informed on their treatment will be emphasised. Pertinent patient related supporting documents such as the Patient Alert Card will be provided to facilitate this activity.

## Additional information

The prescribing oncologist/haematologist will be requested to provide the following information by completing an Initial Application and Drug Supply Request for each patient to be enrolled on to the program for eligibility assessment:

- Patient's initials
- Year of birth
- Gender
- Diagnosis
- Height and Weight
- Previous treatments for DLBCL
- Transplant eligible (Y/N)
- ECOG Performance Status
- Comorbidities
- Concomitant medications

Roche will also provide a physician agreement and the safety data exchange agreement for signature. This document outlines the requirements for reporting AEs in line with the instructions below. Once signed documents are returned by the oncologist, Roche will arrange safety training and delivery of the AE management guide and the patient alert card to the HCPs. The safety training will contain the instructions on recognising, managing and reporting AEs.

Upon receipt of fully signed documents and completion of safety training, Roche will arrange initial drug shipment to cover two cycles of treatment for the patient.

- **Patient Alert Card –** This will be given to all patients before they start treatment. It is a wallet-sized card to be carried at all times to show at all medical visits to HCPs other than the prescribers (e.g. emergency HCPs). It has contact details of the treating physician and it alerts other HCPs physicians that the patient is treated with polatuzumab vedotin. It also contains information on the main symptoms of the important adverse reactions and highlights the importance of notifying the treating physician immediately if symptoms occur, persist or worsen and also the importance of not attempting to self-treat any symptoms without consulting with an HCP first.

For patients approved under this scheme and requiring ongoing drug supply, the HCPs will be required to complete the Re-supply Form provided in the physician pack to request further two cycles of treatment. The HCPs will also be asked for confirmation that they understand and agree to comply with their obligations to report all AEs to Roche and that they are complying with this requirement. They will be also asked to confirm that all AEs experienced since the last re-supply request have been reported and there are no new AEs to report. Roche will produce a quarterly line-listing for all single case reports received in the preceding time period and send this to the Physician. Once received, the Physician will confirm receipt and completeness of the line-listing **within five (5) business days**. This process is referred to as 'Case Transmission Verification (CTV)' in the physician agreement.

HCPs should also report AEs to the MHRA via the Yellow Card scheme, www.mhra.gov.uk/yellowcard, and reporters are requested to state the manufacturer and that the product is unlicensed on the AE report. In addition to this, the EAMS patient ID number should be provided in the report narrative to help the MHRA identify that AE is related to EAMS product and to help Roche link the AE report to the correct EAMS patient.

A 3-monthly periodic safety report will be submitted to the MHRA to summarise data on safety and usage of polatuzumab vedotin under the scheme.

## Contact details

**Contact details for reporting Adverse Events:**

**SAE Email Address:** welwyn.uk_dsc@roche.com

**SAE Facsimile Transmission: +44 1707 367582**

**SAE TELEPHONE CONTACT: +44 1707 367554**

**Name**: UK Drug Safety Centre

**Contact email for the EAMS programme (excluding AE reporting):**

welwyn.polatuzumabeams@roche.com

**Contact Details for Medical Information**

Roche Medical Information on 0800 328 1629 or email medinfo.uk@roche.com