## 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.

**Information on the Pharmacovigilance system:**

When a prescribing oncologist 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) within 24 hours and all non-serious adverse events within 7 days of first knowledge of such events. Although pregnancy, overdose, cancer and drug-induced liver injury (DILI) are not always serious by regulatory definition, these events must be handled as SAEs.

If only limited information is initially available, further follow-up will be requested by the company and all events will be followed to resolution or stabilisation.

**Training for Healthcare Professionals (HCPs)**

Once the prescribing oncologist signs a Letter of Agreement, the company will arrange a site visit for the purposes of delivery of programme materials and training on recognising, managing and reporting of adverse events. The programme materials provided will also include the following:

- **Adverse Reaction Management Guide**
  This guide will ensure understanding of the immunologic aetiology of important adverse reactions, the requirement for more frequent monitoring and/or unique interventions and the guidelines for the management of adverse reactions.

- **Patient Alert Card**
  This is a wallet-sized card to be carried at all times to show at all medical visits to HCPs other than the prescriber (e.g., emergency HCPs). It has contact details of the treating physician and it alerts other physicians that the patient is treated with nivolumab. During the training, the HCP will be instructed to provide a Patient Alert Card to each patient prior to starting treatment.

**Additional information:**

Provision of nivolumab through EAMS is designed to provide early access to this medicine for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults, prior to licensing the product in the UK.

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

- Patient age
- Patient gender
- Histology of primary tumour
- Previous treatment and current medications
- Underlying co-morbidities

Every two weeks following commencement of treatment, the company will collect updated patient data on a short Case Report Form. This will also include, the start date of treatment (once only), drug dose (including any changes in dose) and stop date of treatment if applicable. New concomitant medications will be requested along with confirmation that adverse events have been reported as per the instructions in the programme materials or to confirm that there have been no adverse events.

All adverse event data reported will be entered into the BMS safety database and will be linked to the patient by the assigned EAMS Protocol Number and unique patient number. Data on the safety and usage of the product under the scheme will be discussed in periodic reports submitted to the MHRA.

**Patient Alert Card**
Before treatment starts, all patients will have the scheme explained to them by the prescribing oncologist or specialist nurse and will be given a Patient Alert Card.

**Contact details:**

**Contact details for reporting AEs:**

**Email Address:** drugsafety.uk@bms.com

**Facsimile Transmission:** 01895 523677

**Telephone Contact:** 01895 523735 (or 0800 731 1736 for out of hours contact)

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

EAMS@bms.com