

Early Access to Medicines Scientific Opinion - Public Assessment Report	
Product	Atezolizumab
Condition	Atezolizumab is used to treat advanced cancer of the bladder and urinary system, which has spread and come back after one course of standard cancer chemotherapy
Full indication	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma after disease progression following one prior platinum-containing chemotherapy regimen regardless of its setting (neoadjuvant, adjuvant, or metastatic)
Company	Roche Products Limited
EAMS number	00031/0001

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines to UK patients that have a high unmet clinical need. The MHRA scientific opinion provides benefit and risk information to doctors, who may wish to prescribe the unlicensed medicine under their own responsibility. More information about the scheme can be found here:

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

The scientific opinion is based on the information supplied to the MHRA on the benefits and risks of a promising new medicine. As such this is a scientific opinion and should not be regarded as a medicine licensed by the MHRA or a future commitment by the MHRA to licence such a medicine. The General Medical Council's guidance on prescribing unlicensed medicines can be found here: <http://www.gmc-uk.org/mobile/news/14327>

What is atezolizumab?

Atezolizumab is the active substance of a medicine, which is available as a concentrated solution (liquid) that is diluted for infusion (drip) into a vein.

What is atezolizumab used to treat?

Atezolizumab is used to treat adults with advanced cancer of the bladder and urinary system (urothelial carcinoma), which has spread and come back following one course of standard cancer chemotherapy.

How is atezolizumab used?

Treatment with atezolizumab should be started and supervised by a specialist doctor experienced in treating cancer.

The doctor will carry out blood tests to check the patient's functions before and during treatment.

Atezolizumab is given as an infusion into a vein every three weeks for as long as the patient keeps benefitting from treatment or until it is no longer tolerated. The recommended dose for each infusion is 1,200 mg given over 60 minutes for the first infusion, then 30 minutes if well tolerated.

How does atezolizumab work?

Atezolizumab is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) that is found in certain cells in the body. Atezolizumab has been designed to attach to and block the activity of a protein called PD-L1, which is found on the surface of tumour and immune cells. By blocking PD-L1, atezolizumab restores the capacity of immune cells to fight cancer cells. Atezolizumab works best if the tumour exhibits a certain level of PD-L1, which can be measured in a tumour biopsy.

How has atezolizumab been studied?

The main study of the effects of atezolizumab has enrolled 311 patients with locally advanced or metastatic urothelial carcinoma, which had spread and come back after standard cancer chemotherapy.

The measures of effectiveness (how well the medicine worked) were the growth of the tumour, overall survival (how long the patients lived), and progression-free survival (how long the patients lived without their cancer getting worse).

What benefits and risks has atezolizumab shown during the studies?

Benefits

Tumour shrinking was observed in 16% of the whole population of patients treated with atezolizumab and 37% were still alive after 12 months. When the tumour exhibited a high level of protein PD-L1, shrinking was observed in 28% of the patients and 50% were still alive after 12 months.

Risks

Atezolizumab may be associated with side effects resulting from excessive activity of the immune system, including endocrine abnormalities (e.g. hypothyroidism, diabetes), diarrhoea/colitis, hepatitis, pneumonitis, and rash. Most will resolve following appropriate treatment or on stopping atezolizumab.

The most frequent side effects, affecting at least 20% of the patients, were fatigue (tiredness), decreased appetite, nausea (feeling sick), and dyspnoea (shortness of breath).

Why has atezolizumab been given a positive Early Access to Medicine Scientific opinion?

Atezolizumab has been shown to slow the progression of cancer and increase patient survival in a condition where other treatments currently have poor results (about 20% of patients alive after 12 months). With regard to the medicine's side effects, the most frequent were mild to moderate in severity and less frequent than with chemotherapy. Advanced cancer of the bladder and urinary system is a fatal condition and currently few therapies are available with low efficacy.

What are the uncertainties?

The effects of atezolizumab have not been compared to those of current treatments for advanced bladder cancer in the same study, which is needed to measure its effectiveness more precisely. The company that makes atezolizumab has committed to provide further data when they become available.

Are there on-going clinical studies?

There is an on-going study in locally advanced and metastatic urothelial carcinoma where atezolizumab is compared with standard chemotherapies.

What measures are in place to monitor and manage risks?

A risk management plan has been developed to ensure that atezolizumab is used as safely as possible. Based on this plan, the company that makes atezolizumab must ensure that all healthcare professionals expected to use the medicine, as well as patients, are provided with information on the medicine including the side effects related to the excessive activity of the immune system and recommendations for minimising these side effects.

Information will be collected about patients before they enter the scheme. Healthcare professionals will be asked by the company to report adverse effects experienced by patients receiving atezolizumab through the scheme. These safety data will be reviewed and reported to the MHRA on a regular basis by the company.

Patients in the Early Access to Medicines Scheme will also receive an alert card from their doctor summarising the important risks with the medicine and the details of their treating oncologist. Patients should carry the card with them at all times in case they need treatment or advice from a healthcare professional that is not familiar with atezolizumab treatment.

Other information about atezolizumab – see FAMS Treatment Protocol

Withdrawn