Empliciti® (elotuzumab)

This Horizons Infosheet contains information on Empliciti (also known as elotuzumab), a drug being investigated for the treatment of myeloma.

The Horizons Infosheet series provides information relating to novel drugs that are currently being investigated for the treatment of myeloma. The series also aims to highlight the considerable amount of research currently taking place in the field of myeloma drug development.

The drugs described in the Horizons Infosheets may not be licensed and/or approved for use in myeloma. You may, however, be able to access them as part of a clinical trial.

What is Empliciti?

Empliciti is a new drug being investigated for the treatment of myeloma.

Empliciti is a monoclonal antibody which attaches to a specific protein that is present on the surface of myeloma cells.

What is a monoclonal antibody?

Monoclonal antibodies are a class of drug being investigated in the treatment of myeloma.

Monoclonal antibodies are made in the laboratory to mimic the antibodies that your own immune system produces in response to foreign organisms (such as bacteria) that enter the body. 'Monoclonal' means all one type. This means that each group of monoclonal antibodies is made up of identical copies of one type of antibody.

Monoclonal antibodies are designed to recognise and attach to specific proteins on the surface of cancer cells. Each group of monoclonal antibody recognises one particular protein.

How does Empliciti work?

Myeloma cells produce a protein called SLAMF-7 which is present on the cell surface. Empliciti attaches to the SLAMF-7 protein found on the surface of myeloma cells, enabling the immune system to target and destroy it. See Figure 1.

How is Empliciti given?

Empliciti is given by intravenous infusion (into a vein). The optimal dose and frequency of infusions is still being investigated but in clinical trials to date, patients have been treated with doses of 10mg and 20mg per kg of body weight.

Empliciti appears to be most effective against myeloma cells

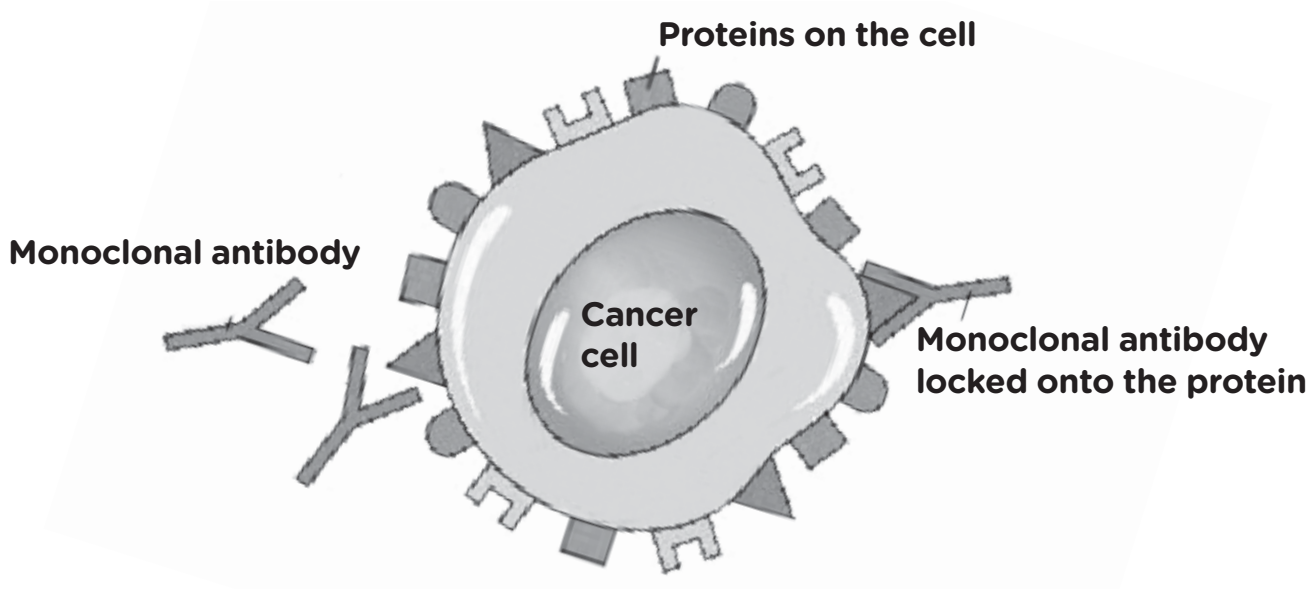

Figure 1. Diagram showing a monoclonal antibody attached to a cancer cell

when combined with other anti-myeloma treatments than when used on its own.

What evidence exists to support the use of Empliciti?

Results from the Phase III ELOQUENT-2 clinical trial showed that patients who received Empliciti, Revlimid® (lenalidomide) and dexamethasone had a 30% reduction in the risk of disease progression compared to those who had Revlimid and dexamethasone alone.

In addition to reduced risk of disease progression, patients in the Empliciti group experienced a longer period of remission - 19.4 months on average compared with 14.9 months for those who had Revlimid and dexamethasone alone. Importantly, patients receiving the Empliciti combination did not appear to have increased side-effects, compared to those who took the standard combination.

What are the possible known side-effects of Empliciti?

The most commonly observed side-effects of Empliciti occur within three to four hours of receiving the intravenous infusion. These include fever, chills, cough, nausea, changes in blood pressure, flushing, rash and fatigue. Other less commonly reported side-effects include: low white blood cell levels (lymphopenia); low platelet levels (thrombocytopenia); low red blood cell levels (anaemia); fatigue; diarrhoea and low potassium levels.

Is Empliciti currently available in any UK clinical trials?

For an up-to-date list of UK clinical trials involving Empliciti, visit the Myeloma Trial Finder on www.myeloma.org.uk

To be enrolled on a clinical trial, patients have to meet certain conditions known as eligibility criteria. You should speak to your doctor in the first instance if you are interested in taking part in a trial.

Availability of Emplicti in the UK

Before a drug can be widely used, it must first be licensed as a safe and effective treatment. This is usually done by regulatory authorities at a European level and involves a review of evidence from large-scale clinical trials.

Normally, the licensed drug must then be approved by a UK drug appraisal body before it can be routinely prescribed by NHS doctors. The drug appraisal process differs from licensing - it compares how effective the newly-licensed drug is to existing drugs already in use on the NHS and decides whether it offers the NHS good value for money. The main body responsible for carrying out drug appraisals in England and Wales is the National Institute for Health and Care Excellence (NICE). NICE recommendations are usually adopted in Northern Ireland. Scotland's drug appraisal body is the Scottish Medicines Consortium (SMC).

In May 2014 Empliciti was granted breakthrough therapy designation by the US licensing body, the Food and Drug Administration (FDA). Breakthrough therapy designation is an accelerated review process for a drug that early clinical evidence indicates may demonstrate substantial improvement over available treatments.

The FDA approved Empliciti, in combination with Revlimid and dexamethasone, for myeloma patients who have received one or more prior therapies in December 2015.

The European licencing board, the European Medicines Agency (EMA), has granted an accelerated assessment for Empliciti for myeloma patients who have received one or more prior therapies.

Accelerated assessment means that the EMA will fast-track Empliciti through their licensing processes, to enable it to become available to patients sooner.

Empliciti is not currently licensed for use in myeloma in the UK and is only accessible to patients as part of a clinical trial.

Future directions

There are several ongoing clinical trials around the world investigating Empliciti and how well it works in patients with relapsed and/or refractory and newly diagnosed myeloma. It is also being studied in patients with high-risk smouldering myeloma and in myeloma patients with poor kidney function.

In addition to Revlimid and dexamethasone, Empliciti is also being studied in combination with treatments such as Velcade® (bortezomib) and thalidomide.

These studies will provide information about the safest and most effective way to use Empliciti in myeloma.

About this Horizons Infosheet

The information in this Horizons Infosheet is not meant to replace the advice of your medical team. They are the people to ask if you have questions about your individual situation. All Myeloma UK publications are extensively reviewed by patients and healthcare professionals prior to publication.

Other information available from Myeloma UK

Myeloma UK has a range of Essential Guides, Infoguides and Infosheets available covering many areas of myeloma, its treatment and management.

To order your free copies or to talk to one of our Myeloma Information Specialists about any aspect of myeloma, call the **Myeloma Infoline: 0800 980 3332** or **1800 937 773** from Ireland.

The Myeloma Infoline is open from Monday to Friday, 9am to 5pm and is free to phone from anywhere in the UK and Ireland. From outside the UK and Ireland, call **0131 557 9988** (charged at normal rate).

Information and support about myeloma is also available around the clock at **www.myeloma.org.uk**

Notes

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