Elotuzumab (Empliciti®)

Horizons Infosheet
Clinical trials and novel drugs

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

The Horizons Infosheet series provides information relating to novel drugs and treatment strategies 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.

The drugs and treatment strategies 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 Elotuzumab?

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

Elotuzumab 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 made in the laboratory to mimic the antibodies that your own immune

system produces in response to foreign organisms (such as bacteria) or abnormal cells. Antibodies recognise proteins on the surface of harmful or abnormal cells and flag them for destruction by the immune system.

Monoclonal antibody drugs are designed to recognise and attach to specific proteins on the surface of cancer cells. 'Monoclonal' means all one type. This means that each group of monoclonal antibodies is made up of identical copies of one type of antibody and recognises one particular protein.

For more information see the **Immunotherapy Horizons Infosheet** from Myeloma UK

How does elotuzumab work?

Myeloma cells produce a protein called SLAMF7 which is present on the cell surface in large amounts. Elotuzumab attaches to the SLAMF7 protein, enabling the immune system to target and destroy the myeloma cells (Figure 1).

Elotuzumab also attaches to SLAMF7 on a type of immune cell called natural killer cells. This causes the natural killer cells to attack myeloma cells.

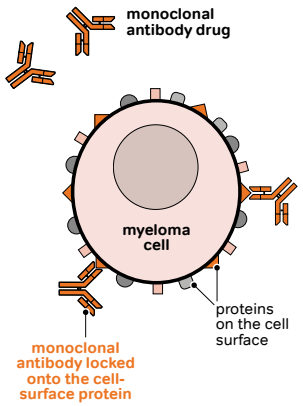

Figure 1. Mechanism of action of monoclonal antibody drugs

How is elotuzumab given?

Elotuzumab is given by intravenous infusion (into a vein). The usual dose is 10mg per kilogram of body weight once a week for the first two cycles. For subsequent cycles, a dose of 10mg or 20mg per kilogram of body weight, once every two or four weeks, is given.

Elotuzumab appears to be most effective against myeloma cells when combined with other anti-myeloma treatments.

What evidence exists to support the use of elotuzumab?

The key clinical trials supporting the use of elotuzumab in relapsed and refractory myeloma were the ELOQUENT-2 and ELOQUENT-3 trials.

In the ELOQUENT-2 clinical trial, 321 patients with relapsed or refractory myeloma were given elotuzumab, lenalidomide and dexamethasone (ERd), and 325 were given lenalidomide and dexamethasone only (Rd). In this trial, the average progression-free survival (meaning time before the myeloma starts to come back) was longer for patients given ERd (19.4 months, compared with 14.9 months for Rd). This difference was still seen in the final follow-up after 70.6 months, and the time the patients eventually lived was also longer on average for the ERd group.

In the ELOQUENT-3 clinical trial, 60 patients with relapsed or refractory myeloma were given elotuzumab, pomalidomide and dexamethasone, and 57 were given pomalidomide and dexamethasone only. In this trial, the average progression-free survival was longer for patients given the elotuzumab combination (10.3 months, compared with 4.7 months for pomalidomide and dexamethasone only). The overall response rate (a partial response or better to treatment) was 53% (53 in 100) in the elotuzumab combination compared with 26% (26 in 100) for pomalidomide and dexamethasone only.

In a separate clinical trial in newly diagnosed myeloma patients called ELOQUENT-1, 371 patients were given elotuzumab, lenalidomide and dexamethasone, and 371 patients were given lenalidomide and dexamethasone only. In this trial no difference was seen between the two treatments in terms of progression-free survival.

What are the possible known side effects of elotuzumab?

The most commonly observed side effects of elotuzumab include:

- Infusion reactions (reactions that occur within three to four hours of receiving the intravenous infusion). Symptoms include fever, chills and changes in blood pressure
- Infections (including pneumonia)
- Low white blood cell levels (leukopenia)
- Deep vein thrombosis (blood clots in the veins)
- Fatigue

- Diarrhoea
- Headache
- Cough

Because elotuzumab is a relatively new drug, new side effects may emerge which have not yet been reported.

Is elotuzumab currently available in any UK clinical trials?

For an up-to-date list of UK clinical trials involving elotuzumab, visit the Myeloma Trial Finder on 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.

If you are considering taking part in a clinical trial your doctor will discuss in detail the risks and benefits for you. They will give you detailed information to enable you to make an informed decision about whether to take part.

Availability of elotuzumab in the UK

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

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. Elotuzumab has been licensed by the European Medicines Agency (EMA) for use in relapsed and refractory myeloma. The licence is for two combinations: elotuzumab, lenalidomide and dexamethasone; and elotuzumab, pomalidomide and dexamethasone.

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).

Elotuzumab has not been submitted to NICE or the SMC for use in myeloma. Therefore it is not approved for use on the NHS in the UK.

For more information see the **Health Technology Assessment Infosheet** from Myeloma UK

Future directions

Elotuzumab continues to be studied in different combinations and different myeloma patient groups. This includes patients with relapsed and/or refractory and newly diagnosed myeloma.

In addition to lenalidomide, pomalidomide and dexamethasone, elotuzumab is also being studied in combination with treatments such as carfilzomib (Kyprolis®) and autologous stem cell transplantation.

Other potential myeloma treatments targeting the same protein as elotuzumab (SLAMF7) are also being studied.

Key points

- Elotuzumab is a drug being investigated in the treatment of myeloma
- Elotuzumab is a monoclonal antibody drug which targets the SLAMF7 protein found on the surface of myeloma cells
- Elotuzumab has been licensed for use in Europe in combination with other anti-myeloma drugs for relapsed and refractory patients
- Elotuzumab is not yet widely available in the UK because it has not been approved for use in myeloma on the NHS. However, patients may be treated with it as part of a clinical trial
- Side effects seen so far include infusion reaction, infections and low white blood cell levels

About this Infosheet

The information in this 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.

For a list of references used to develop our resources, visit myeloma.org.uk/references

We value your feedback about our patient information.
For a short online survey go to myeloma.org.uk/pifeedback or email comments to patientinfo@myeloma.org.uk

Other information available from Myeloma UK

Myeloma UK has a range of publications available covering all aspects of myeloma, its treatment and management. Download or order them from myeloma.org.uk/publications

To talk to one of our Myeloma Information Specialists about any aspect of myeloma, call our Myeloma Infoline on 0800 980 3332 or 1800 937 773 from Ireland.

The Infoline is open from Monday to Friday, 9am to 5pm and is free to phone from anywhere in the UK and Ireland.

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

Notes

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MyelomaUK

We're here for everything a diagnosis of myeloma brings

Get in touch to find out more about how we can support you

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