

## Myeloma UK

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Myeloma Awareness Week

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# Daratumumab

## Introduction

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 daratumumab?

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

Daratumumab (originally known as HuMax-CD38) is a monoclonal antibody which attaches specifically to a 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 daratumumab work?

Myeloma cells produce a protein called CD38 which is present on the cell surface. Daratumumab attaches to the CD38 protein found on the surface of myeloma cells, enabling the immune system to target and destroy it. See Figure 1.

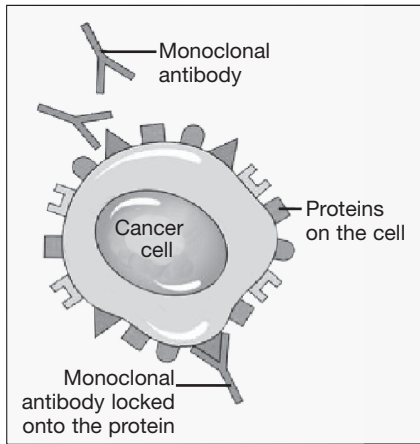


Figure 1. Diagram showing a monoclonal antibody attached to a cancer cell  
© CancerHelp UK

### How is daratumumab given?

Daratumumab is given by intravenous infusion (into a vein). The optimal dose and frequency of infusions is still being investigated but commonly used doses in clinical trials have been 8 and 16 milligram per kilogram (mg/kg) at differing dosing intervals.

Daratumumab can be given as a monotherapy (i.e. used on its own and not in combination with other drugs) but it has been shown to be most effective when used in combination with other anti-myeloma treatments such as dexamethasone, Velcade® (bortezomib) and Revlimid® (lenalidomide).

Trials are being carried out in both newly diagnosed and relapsed and/or refractory patients.

### What evidence exists to support the use of daratumumab?

Of 20 relapsed and/or refractory patients (who had received an average of four prior treatments) given 16mg/kg doses of daratumumab in a Phase II clinical trial, 35% responded, of which 10% achieved a complete response (no detectable paraprotein).

### What are the possible known side-effects of daratumumab?

The most commonly observed side-effects of daratumumab 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. These are typically more likely to occur with the first infusion rather than second or subsequent.

Other side-effects reported include: low white blood cell levels (lymphopenia); low platelet levels (thrombocytopenia); low red blood cell levels (anaemia) and elevated liver enzymes.

### Is daratumumab currently available in any UK clinical trials?

There are currently (Sept 2014) three clinical trials involving daratumumab in the UK.

- A Phase I/II trial studying daratumumab in combination with Revlimid in dexamethasone\*
- A Phase III trial studying daratumumab in combination with Revlimid and dexamethasone in relapsed and/or refractory myeloma patients\*\*
- A Phase III trial studying daratumumab in combination with Velcade, melphalan and prednisolone in newly diagnosed patients\*\*\*

\* Recruiting UK hospitals/institutions: Sarah Cannon Research Institute, London; St Bartholemew's Hospital, London

\*\* Recruiting UK areas: Birmingham, Leeds, London, Oxford, Southampton, Surrey, Wolverhampton

\*\*\* Not yet recruiting

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 daratumumab 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 2013, daratumumab received a “breakthrough therapy designation” by the US licensing body, the Food and Drug Administration (FDA) for the treatment of myeloma patients who have received at least three previous treatments, including a proteasome inhibitor (such as Velcade) and an immunomodulatory drug (such as Revlimid). Breakthrough therapy designation is an accelerated review process for a drug that early clinical evidence indicates may demonstrate substantial improvement over available treatments.

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

### The future

Daratumumab continues to be studied in different patient groups and in different treatment combinations. These trials will provide information about the safest and most effective way to use daratumumab 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 call our **Myeloma Infoline on 0800 980 3332**. This information is also available on our website at [www.myeloma.org.uk](http://www.myeloma.org.uk)

To talk to one of our Myeloma Information Specialists about any aspect of myeloma, call the **Myeloma Infoline on 0800 980 3332**. 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, call +44 (0)131 557 9988 (charged at normal rate). Information and support about myeloma is also available around the clock at [www.myeloma.org.uk](http://www.myeloma.org.uk)

## About Myeloma UK

Myeloma UK is the only organisation in the UK dealing exclusively with myeloma, a bone marrow cancer for which there is no cure, but many very effective treatments.

Our broad and innovative range of services cover every aspect of myeloma from providing information and support, to improving standards of treatment and care through research and campaigning.

## With Myeloma UK you can...

- Call our **Myeloma Infoline** on **0800 980 3332** for information, practical advice, emotional support and a listening ear
- Get free Infopacks, Infoguides and Infosheets about myeloma
- Learn about myeloma from experts and meet others affected by myeloma by attending Patient and Family Myeloma Infodays
- Subscribe to our magazine *Myeloma Matters*
- Visit our website [www.myeloma.org.uk](http://www.myeloma.org.uk)
- Join a Myeloma Support Group

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