Reolysin®

This Horizons Infosheet contains information on Reolysin, an oncolytic virus 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 in 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 Reolysin?

Reolysin, also known as pelareorep, is a type of oncolytic virus being investigated for the treatment of myeloma and various other cancers.

Oncolytic viruses infect and kill cancer cells. At the same time, they cause the immune system to launch an immune response against the cancer cells, so their action against

the cancer cells is increased.

How does Reolysin work?

When Reolysin infects a myeloma cell, it creates copies of itself within the cell until the cell bursts. This causes the myeloma cell to die and release the virus into the surrounding area (Figure 1). The virus then goes on to infect and kill other myeloma cells.

In addition to directly killing myeloma cells, the presence of Reolysin also stimulates the immune system to launch an immune response against myeloma cells. The immune system is made up of specialised cells, tissues and organs which can identify and kill faulty or abnormal cells in the body, and protect the body from foreign organisms (such as bacteria or viruses).

How is Reolysin given?

Reolysin is given as an intravenous (IV) infusion over one hour. How often Reolysin is given (i.e. the number of 'doses') is still being investigated in clinical trials.

Reolysin has been shown to work against myeloma when given on its own; however, evidence suggests that its anti-myeloma effects are enhanced when it is given in combination with other anti-myeloma drugs such as bortezomib (Velcade®).

What evidence exists to support the use of Reolysin in myeloma?

Reolysin has been studied in the laboratory using myeloma cells and other cancer cells, with promising

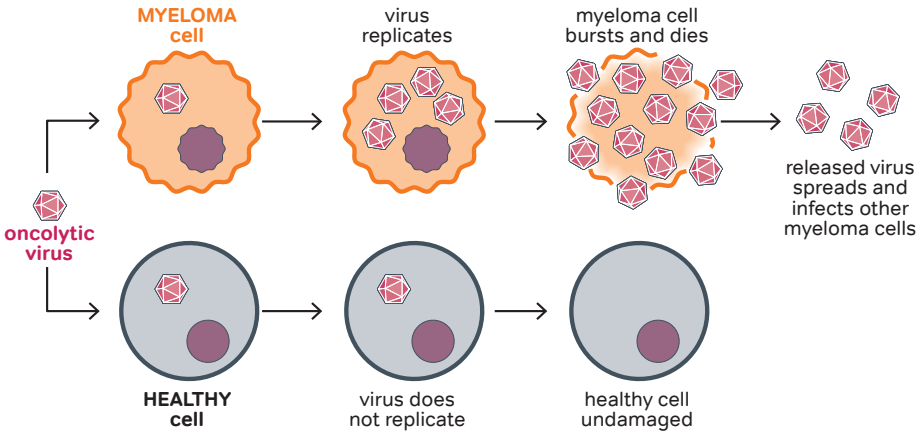

Figure 1. How oncolytic viruses work

results. Due to these results, Reolysin has recently entered early phase clinical trials in myeloma patients.

Initial findings from a small phase I trial of Reolysin given on its own to 12 multiply relapsed myeloma patients showed it to be well tolerated with some evidence of response in nearly half of the patients (prolonged plateau/stable disease).

Reolysin is also being studied in combination with carfilzomib (Kyprolis®), a proteasome inhibitor similar to bortezomib, to investigate whether the combination will lead to an increased response. This small phase I trial is investigating the response to Reolysin and carfilzomib in multiply relapsed patients with high-risk myeloma (a more active or more difficult to treat myeloma), some of whom no longer respond to bortezomib. Initial results show the majority of patients (6 of 7 patients - 86%) exhibited a response to the combination.

The combination of Reolysin with immunomodulatory drugs (drugs which act upon the immune system), such as lenalidomide (Revlimid®), is also being investigated. For example, a Myeloma UK-funded trial, MUK eleven, aims to study the effects of Reolysin in combination with lenalidomide or another immunomodulatory drug, pomalidomide (Imnovid®), as a treatment for relapsing myeloma patients.

The aim is to determine whether the combination of pomalidomide or lenalidomide and Reolysin can increase immune activation, leading to better control of the myeloma.

What are the possible known side effects of Reolysin?

Reolysin is a laboratory-made version of a naturally occurring virus belonging to the reovirus family of viruses.

Natural reovirus infection causes minor symptoms such as sore throat, sneezing and sniffles, mild diarrhoea, or sometimes no symptoms at all. It is estimated that between 70 - 100% of adults have been infected with a reovirus at some point during their life. To date, the most commonly seen side effects of Reolysin in clinical trials with myeloma patients have been similar to those seen with natural reovirus infection: mild to moderate diarrhoea, fatigue, headache and flu-like symptoms.

Is Reolysin currently available in any UK clinical trials?

For an up-to-date list of UK clinical trials involving Reolysin, 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 Reolysin in the UK

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

Normally, the licensed drug or treatment 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 or treatment is to existing NHS treatment 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).

For more information see the Health Technology Assessment (HTA) Infosheet from Myeloma UK

Reolysin 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

To date, Reolysin has produced encouraging results in other advanced-stage cancers, and early phase results in myeloma show it to be well tolerated and potentially effective when used in combination with other myeloma drugs. It continues to be studied in different patient groups and in different combinations. These trials will provide information about the safest and most effective way to use Reolysin in myeloma.

If it continues to do well in clinical trials, Reolysin would be the first oncolytic virus to be approved for use in myeloma, and would represent a new treatment strategy 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.

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

To provide feedback about this publication, email **myelomauk@myeloma.org.uk**

Other information available from Myeloma UK

Myeloma UK has a range of publications available covering all 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 our Myeloma UK 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 **www.myeloma.org.uk**

Notes

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