

## What is BLENREP?

BLENREP is a prescription medicine used to treat adults with multiple myeloma who have received at least 4 prior medicines to treat multiple myeloma, **and** their cancer has come back or did not respond to prior treatment. It is not known if BLENREP is safe and effective in children.

BLENREP is approved based on patient response rate. Studies are ongoing to confirm the clinical benefit of BLENREP for this use.

#### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about BLENREP?

Before you receive BLENREP, you must read and agree to all of the instructions in the BLENREP REMS. Before prescribing BLENREP, your healthcare provider will explain the BLENREP REMS to you and have you sign the Patient Enrollment Form.

## **BLENREP** can cause serious side effects, including:

**Eye problems.** Eye problems are common with BLENREP. BLENREP can cause changes to the surface of your eye that can lead to dry eyes, blurred vision, worsening vision, severe vision loss, and corneal ulcer. Tell your healthcare provider if you have any vision changes or eye problems during treatment with BLENREP.

REMS=Risk Evaluation and Mitigation Strategy.

Please see IMPORTANT SAFETY INFORMATION continued throughout and accompanying full Prescribing Information, including BOXED WARNING and Medication Guide.

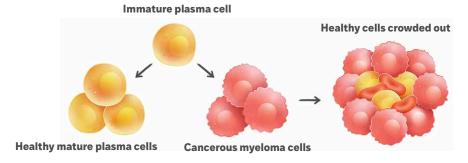


# How does multiple myeloma occur?

## Understanding the course of multiple myeloma

Multiple myeloma is a blood cancer that starts in plasma cells, a type of white blood cell that normally fights infections. Multiple myeloma develops after healthy plasma cells, located in the bone marrow, mutate into cancerous myeloma cells.

The cancerous myeloma cells grow uncontrollably, crowding out new healthy blood cells made in the bone marrow, including red blood cells, white blood cells, and platelets. The cancerous myeloma cells can overtake normal blood cells in the bone marrow, destroy bone tissue, and spread all over the body.



# Multiple myeloma does not have a cure, but it can be treated with help from healthcare providers when it relapses

Not all patients respond to a treatment the same way. Relapse is the return of the disease or signs and symptoms of the disease after a period of improvement. When cancer does not respond to a treatment, it is known as refractory disease.

ALTHOUGH IT'S DISCOURAGING WHEN RELAPSE OCCURS, THERE ARE TREATMENT OPTIONS AVAILABLE

# **IMPORTANT SAFETY INFORMATION (CONT'D)**

- Your healthcare provider will send you to an eye specialist to check your eyes before you start treatment with BLENREP, prior to each dose of BLENREP, and for worsening symptoms of eye problems.
- Even if your vision seems fine, it is important that you get your eyes checked during treatment with BLENREP because some changes can happen without symptoms and may only be seen on an eye exam.
- You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.
- You should use caution when driving or operating machinery as BLENREP may affect your vision.
- Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye specialist.

**Decrease in platelets (thrombocytopenia)** is common with BLENREP, and can also be serious. Platelets are a type of blood cell that help your blood to clot. Your healthcare provider will check your blood cell counts before you start treatment with BLENREP and during treatment. Tell your healthcare provider if you have bleeding or bruising during treatment with BLENREP.

### What is BLENREP?



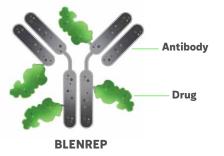
BLENREP is a prescription medicine used to treat multiple myeloma in adults whose cancer has come back or did not respond to prior treatment and who have already received at least 4 prior therapies, including at least 1 therapy from each of these classes of drugs:

- an immunomodulatory agent (for example, Revlimid [lenalidomide], Pomalyst [pomalidomide], or Thalomid [thalidomide])
- a proteasome inhibitor (for example, Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])
- an anti-CD38 monoclonal antibody (for example, Darzalex [daratumumab])

Ask your healthcare provider to ensure you have received at least 1 of each of these treatments.

BLENREP is approved based on patient response rate. Studies are ongoing to confirm the clinical benefit of BLENREP for this use.

BLENREP is an antibody-drug conjugate (ADC) targeting B-cell maturation antigen (BCMA). It works in unique ways to help fight multiple myeloma.



#### What is an ADC?

An ADC is made of a cell-killing medication attached to an antibody.\* The antibody of BLENREP seeks out and targets BCMA, a protein found on the surface of multiple myeloma cells in all patients. The linked drug can then enter and kill multiple myeloma cells from the inside or activate your immune system to fight your cancer.

BLENREP IS THE FIRST AND ONLY ADC THAT TARGETS BCMA, COMMONLY SEEN ON MYELOMA CELLS
IT IS POSSIBLE THAT HEALTHY CELLS MAY ALSO BE AFFECTED

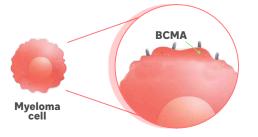
\*An antibody is a type of protein produced by the immune system in response to a foreign substance. Sometimes treatments can use antibodies to help fight cancer.

# BCMA is a protein found on the surface of myeloma cells in all patients with multiple myeloma

BCMA is found on healthy plasma cells and cancerous myeloma cells alike and:

- helps fuel cell growth
- protects cells from dying

BCMA is found at higher levels on myeloma cells.



BCMA IS SHAPED BY ALL MULTIPLE MYELOMA PATIENTS

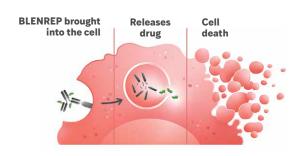
### **How does BLENREP work?**

BLENREP works in different ways to help your body fight multiple myeloma:



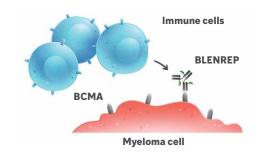
BLENREP identifies cells that express BCMA, such as cancerous myeloma cells, and attaches directly to the BCMA protein. BLENREP is brought into the cancerous myeloma cells, releasing medication resulting in cell death.\*







Once BLENREP attaches, the antibody part of the ADC attracts your body's own immune system to recognize the cancerous myeloma cells and attack them.



BLENREP, AN OPTION AFTER RELAPSE, WORKS IN DIFFERENT WAYS, INCLUDING USING YOUR BODY'S OWN IMMUNE SYSTEM

# **IMPORTANT SAFETY INFORMATION (CONT'D)**

**Infusion reactions** are common with BLENREP, and can also be serious. Tell your healthcare provider or nurse right away if you get any of the following signs or symptoms of an infusion reaction while receiving BLENREP:

- chills or shaking
- redness of your face (flushing)
- itching or rash
- shortness of breath, cough, or wheezing
- swelling of your lips, tongue, throat, or face
- dizziness
- feel like passing out
- tiredness
- fever
- feel like your heart is racing (palpitations)

**The most common side effects of BLENREP include** vision or eye changes such as findings on eye exam (keratopathy), decreased vision or blurred vision, nausea, low blood cell counts, fever, infusion-related reactions, tiredness, and changes in kidney or liver function blood tests.

# **How was BLENREP studied?**



Two doses of BLENREP were evaluated (studied) in patients with **relapsed or refractory multiple myeloma**. The results below only include the 97 patients who received the recommended dose of BLENREP. About a quarter of these patients had high-risk cytogenetics [presence of t(4;14), t(14;16), or 17p13del mutations].

These patients had received prior treatment for multiple myeloma, including an anti-CD38 antibody, and were no longer responding to an immunomodulatory agent and to a proteasome inhibitor.

# How did people respond to BLENREP?

**Approximately** 

1 in 3

(31%)

experienced a response to treatment



Response was seen in patients whose cancer had returned or progressed multiple times. Patients in the trial had received at least 3 and up to 21 prior treatment regimens. Half the patients had received 7 or fewer treatments.

#### IN PATIENTS WHO RESPONDED:

**BLENREP** worked in about

**BLENREP** response lasted

6 WEEKS

AT LEAST 6 MONTHS

for most patients (73%)

BLENREP showed a very good partial response or better

IN 60% OF PATIENTS
(18 out of 30 patients)

In the 97 patients evaluated, 2 patients (2%) had a stringent complete response, 1 (1%) had a complete response, 15 (15%) had a very good partial response, and 12 (12%) had a partial response. These categories describe how well a patient responded to BLENREP.

# **IMPORTANT SAFETY INFORMATION (CONT'D)**

# Before receiving BLENREP, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of vision or eye problems.
- have bleeding problems or a history of bleeding problems.
- are pregnant or plan to become pregnant. BLENREP can harm your unborn baby. Females who are able to become pregnant: Your healthcare provider may do a pregnancy test before you start treatment with BLENREP. You should use effective birth control during treatment with BLENREP and for 4 months after the last dose. Talk to your healthcare provider about birth control methods you can use during this time. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with BLENREP. Males with female partners who are able to become pregnant should use effective birth control during treatment with BLENREP and for 6 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if BLENREP passes into your breast milk. Do not breastfeed during treatment with BLENREP and for 3 months after the last dose.
- BLENREP may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

# What were the most common side effects of BLENREP in the clinical trial?

The most common side effects (≥20%) seen in patients who received the recommended dose of BLENREP were vision or eye changes such as findings on an eye exam (keratopathy\*), decreased vision or blurred vision, nausea, low blood cell counts, fever, infusion-related reactions, tiredness, and changes in kidney or liver function blood tests

These are not all the possible side effects of BLENREP.

Of all the side effects, some led to treatment interruption, dose reduction, and treatment discontinuation:

- 54% of patients experienced a treatment interruption. Side effects that led to an interruption in more than 3% of patients included keratopathy (47%), blurred vision (5%), dry eye (3.2%), and pneumonia (3.2%).
- 29% of patients experienced a dose reduction. Side effects that led to dose reduction in more than 3% of patients included keratopathy (23%) and decreased platelets (5%).
- 8% of patients discontinued treatment permanently. This was most commonly due to keratopathy (2.1%).

Eye problems reported in patients who received the recommended dose of BLENREP included keratopathy (71%), decreased vision (53%), blurred vision (22%), and dry eye (14%).

## Eye problems, which can be serious, were common with BLENREP. In 218 patients who received 2 different doses, the following were seen:

- Eye problems occurred in 77% of all 218 patients in the clinical trial. These included keratopathy (76%), decreased vision (55%), blurred vision (27%), and dry eye (19%).
- Among 165 patients who had keratopathy, 49% had eye symptoms, 65% had a clinically significant change in vision, and 34% had both eye symptoms and changes in vision.
- Of 149 patients with moderate to severe keratopathy, 39% recovered to mild findings or better after a follow-up of approximately 6 months, and the median time to resolution was 2 months (range: 11 days to 8.3 months).
- Of the 61% who had ongoing keratopathy, 28% were still on treatment, 9% were in follow-up, and in 24% the follow-up ended due to stopping participation, being lost to follow-up, or death.
- Of 41 patients who experienced decreased vision of worse than 20/40, 88% resolved, and the median time to resolution was 22 days (range: 7 days to 4.2 months).
- Of 3 patients who experienced decreased vision of 20/200 or worse, all resolved, and the median duration was 22 days (range: 15 to 22 days).

Because of the risk of eye problems, BLENREP is only available through a restricted program called the BLENREP REMS

> IF YOU EXPERIENCE ANY SIDE EFFECTS WHILE TAKING BLENREP, PLEASE CONTACT YOUR HEALTHCARE PROVIDER

## What is the BLENREP REMS?



# A Risk Evaluation and Mitigation Strategy (REMS) is a program to manage known or potential serious health risks associated with a medicine

- Because of the risk of eye problems, BLENREP is only available through a restricted program called the BLENREP REMS.
- Before you receive BLENREP, you must read and agree to all of the instructions in the BLENREP REMS.
- Your healthcare provider will explain the BLENREP REMS to you and have you sign the patient enrollment form.
- You must be enrolled in the BLENREP REMS and follow the REMS requirements for eye exams in order to receive BLENREP.

Further information is available at BLENREPREMS.com and 1-855-209-9188

# How is BLENREP given?



**Treatment infusions can be administered:** 

Over at least 30 MINUTES once every 3 WEEKS

- In your oncologist's or hematologist's office or an outpatient clinic
- By intravenous infusion into your vein as a single agent that doesn't need to be combined with other multiple myeloma medications

## Your healthcare provider will decide on the correct dose of BLENREP for you. The dose is calculated based on your body weight.

- Premedication with steroids is generally not required before your first infusion. If you experience an infusion reaction, your doctor will pause treatment and resume your dose at a slower rate (infused over a longer period of time) after symptoms resolve. Your doctor may consider premedication, including a steroid, for any future infusions.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider may decrease your dose or temporarily stop or completely stop treatment with BLENREP if you have serious side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

<sup>\*</sup>Changes to the surface of your eye found during an eye exam, with or without symptoms, are considered keratopathy.

# **Treatment experience with BLENREP**

#### **Before treatment**



## Tell your healthcare provider about all your medical conditions, including if you:

- Have a history of vision or eye problems
- Have bleeding problems or a history of bleeding problems
- Are pregnant or plan to become pregnant. BLENREP can harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if BLENREP passes into your breast milk

#### Tell your healthcare provider about all the medications you take, including:

- Prescription and over-the-counter medicines
- Vitamins and herbal supplements

#### **Review your REMS Patient Guide prior to your first infusion**



## You will need to receive important exams:

- Eye exam: Your healthcare provider will send you to an eye specialist to check your eyes before you start treatment with BLENREP
- **Pregnancy test:** Your healthcare provider may do a pregnancy test before you start treatment, as BLENREP may harm your unborn baby
- Blood cell counts

IF YOU EXPERIENCE ANY SIDE EFFECTS WHILE TAKING BLENREP, IT IS IMPORTANT TO CONTACT YOUR HEALTHCARE PROVIDER

# **Treatment experience with BLENREP**



## **During treatment**



## Monitor and tell your healthcare provider if you have any symptoms and side effects

- Tell your healthcare provider if you have any vision changes or eye problems during treatment with BLENREP
- Tell your healthcare provider if you have bleeding or bruising during treatment with BLENREP
- Tell your healthcare provider or nurse right away if you get any of the following signs or symptoms of an infusion reaction while receiving BLENREP:
- chills or shaking
- redness of your face (flushing)
- itching or rash
- shortness of breath, cough, or wheezing
- swelling of your lips, tongue, throat, or face
- dizziness
- feel like passing out
- tiredness
- fever
- feel like your heart is racing (palpitations)



#### Eye care is important

- You will receive an eye exam prior to each dose of BLENREP and for worsening symptoms of eye problems as required by the BLENREP REMS. Eye exams are important, as some changes can happen without symptoms and may only be seen on an eye exam
- Use preservative-free lubricant eye drops 4 times each day throughout your treatment with BLENREP as instructed by your healthcare provider. Guidance on using eye drops is provided at eyedropinstructions.com
- Don't wear contact lenses, unless your doctor advises you to. If you normally wear contact lenses, you can plan to use a pair of eyeglasses while taking BLENREP
- Use caution when driving or operating machinery



- It is important for patients who are able to become pregnant, and males with female partners who are able to become pregnant, to use effective contraception.
   Talk to your healthcare provider about birth control methods you can use during this time
- Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with BLENREP
- Do not breastfeed during treatment with BLENREP and for at least 3 months after the last dose

#### **After treatment**



# Talk to your healthcare provider before stopping your contraception

- Males with female partners who are able to become pregnant should use effective contraception and for at least 6 months after the last dose of BLENREP
- Patients who are able to become pregnant should continue to use effective contraception for at least 4 months after the last dose of BLENREP

# **BLENREP** patient support is available

**Support staff** are available to help with your questions and concerns, including:

- What to expect during administration of BLENREP
- What to do if you experience side effects
- Education about multiple myeloma

**Together with GSK Oncology** offers a variety of patient access and reimbursement resources in one easy-to-access location for all GSK oncology products.

Benefits investigation

- Co-pay assistance
- Prior authorization and appeal support
- Eye care appointment scheduling and reminder services
- Cost Savings Plan, for those who are eligible

WE'RE HERE TO HELP ANSWER MANY OF YOUR QUESTIONS ONLINE: BLENREP.COM AND BY PHONE: 1-844-4GSK-ONC (1-844-447-5662) FROM 8 AM TO 8 PM ET

# **REMS** resources available to you

In addition to counseling from your healthcare provider, a REMS Patient Guide with education on the risk and management of eye problems is available. Visit **BLENREPREMS.com** or call **1-855-209-9188** for more information.

• For eligible patients, eye care support is available. Ask your doctor about the **BLENREP Eye Drop Supportive Care Program** to receive preservative-free lubricant eye drops throughout your therapy

SIGN UP AT BLENREP.COM TO RECEIVE INFORMATION AND UPDATES FROM THE PATIENT SUPPORT PROGRAM

# IMPORTANT SAFETY INFORMATION (CONT'D)

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

These are not all the possible side effects of BLENREP.

# **Frequently Asked Questions**



## Who can take BLENREP?

BLENREP is a prescription medicine used to treat adults with multiple myeloma who have received at least 4 prior medicines to treat multiple myeloma, and their cancer has come back or did not respond to prior treatment. It is not known if BLENREP is safe and effective in children.

BLENREP is approved based on patient response rate. Studies are ongoing to confirm the clinical benefit of BLENREP for this use.

## If BLENREP is right for me, how do I become eligible to receive it?

Because of the risk of eye problems, you can only receive BLENREP after you've enrolled in the BLENREP REMS. Your doctor can help you with enrollment.

## How does BLENREP work differently from other multiple myeloma treatment?

BLENREP is the first and only antibody-drug conjugate that targets BCMA, a protein on your multiple myeloma cells. It is possible that healthy cells will be affected.

## **How often should I receive BLENREP?**

BLENREP is an infusion that is administered for at least 30 minutes, usually every 3 weeks. Your healthcare provider will decide how many treatments you need. Your healthcare provider may decrease your dose or temporarily stop or completely stop treatment with BLENREP if you have serious side effects. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

## Do I need to take steroids or other multiple myeloma treatments in combination with BLENREP?

BLENREP is used alone in the treatment of multiple myeloma. However, if you have an infusion-related reaction during treatment, your doctor will pause treatment and resume your dose at a slower rate (infused over a longer period of time) after symptoms resolve. Your doctor may consider premedication, including a steroid, for any future infusions. You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP.

# What most common side effects should I be aware of during treatment with BLENREP?

The most common side effects of BLENREP include vision or eye changes such as findings on eye exam (keratopathy), decreased vision or blurred vision, nausea, low blood cell counts, fever, infusion-related reactions, tiredness, and changes in kidney or liver function blood tests.

These are not all the possible side effects of BLENREP.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### Is there patient support available with BLENREP?

If your healthcare provider has decided that BLENREP is the right treatment option for you, *Together with GSK Oncology* offers a variety of patient access and reimbursement resources. For eligible patients, eye care support is available. Ask your doctor about the **BLENREP Eye Drop Supportive Care Program** to receive preservative-free lubricant eye drops throughout your therapy. Sign up at **BLENREP.com** to receive information and updates from the patient support program.

YOUR HEALTHCARE TEAM IS ALWAYS THE BEST SOURCE FOR ANSWERS TO ANY QUESTIONS ABOUT YOUR HEALTH



To learn more, visit BLENREP.com or call 1-844-4GSK-ONC (1-844-447-5662)

Please see IMPORTANT SAFETY INFORMATION starting on front cover and accompanying full Prescribing Information, including BOXED WARNING and Medication Guide.

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