

\*The people in this study were MRD+. MRD+ means there is molecular evidence of disease that can be seen by a reliable test. They were also in complete remission either for the first or second time. 
†Measured with a test that can detect 1 cancer cell out of 10,000 cells in the bone marrow. (More sensitive testing methods may be able to detect lower levels of cancer cells.)
†People in this study experienced a median of 22.3 months without their cancer returning after treatment with BLINCYTO. A median is the middle number in a set of measurements. 
ALL, acute lymphoblastic leukemia; MRD+, minimal residual disease positive (more than 1 cancer cell per 1,000 cells in the bone marrow).

#### **INDICATION**

BLINCYTO® (blinatumomab) is a prescription medicine used to treat B-cell precursor acute lymphoblastic leukemia (ALL) in patients who still have detectable traces of cancer after chemotherapy.

The approval of BLINCYTO® in these patients is based on a study that measured response rate and duration of response. There are ongoing studies to confirm clinical benefit.

#### IMPORTANT SAFETY INFORMATION

What is the most important information I should know about BLINCYTO®?

- Call your health care provider or get emergency medical help right away if you get any of the symptoms listed below:
  - BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:
    - Cytokine Release Syndrome (CRS) and infusion reactions. Symptoms of CRS and infusion reactions may include: fever, tiredness or weakness, dizziness, headache, low blood pressure, nausea, vomiting, chills, face swelling, wheezing or trouble breathing, and skin rash.



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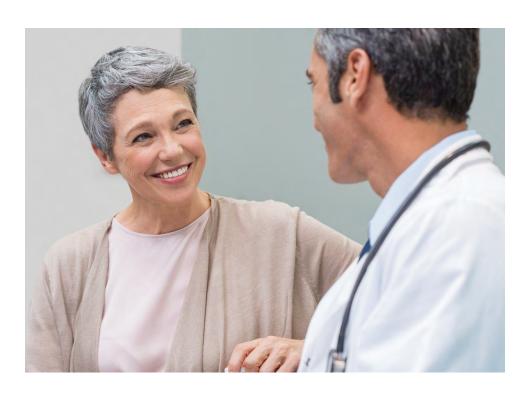
# The goal is to be MRD-1,\*



Cancer can often hide from treatments, making it hard to completely eliminate. Even after achieving **remission** with **chemotherapy**, a small number of cancer cells can remain in your body. This is called **minimal residual disease**, or **MRD**. There are reliable tests to detect MRD.<sup>2</sup>

Any remaining traces of cancer (MRD) can cause a **relapse**.<sup>2</sup> Your doctor's goal is for you to become **MRD-**, which means you do not have detectable traces of cancer left. People who become MRD- are less likely to relapse. This means that they may live disease-free longer than people who are **MRD+**.<sup>3,†</sup>

By now, your doctor may have tested you for MRD after completion of chemotherapy for **acute lymphoblastic leukemia (ALL)**. If not, ask your doctor if an MRD test is right for you.



\*As measured by a test that can detect 1 cancer cell out of 10,000 cells in the bone marrow.<sup>1,2</sup> (More sensitive testing methods may be able to detect lower levels of cancer cells.) <sup>†</sup>Measured in an examination of several studies over 10 years as the length of time people were without signs or symptoms of cancer.<sup>3</sup> MRD-, minimal residual disease negative.

#### IMPORTANT SAFETY INFORMATION

- BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:
  - **Neurologic problems.** Symptoms of neurologic problems may include: seizures, difficulty in speaking or slurred speech, loss of consciousness, trouble sleeping, confusion and disorientation, loss of balance, headache and difficulty with facial movements, hearing, vision, or swallowing.
- Your health care provider will check for these problems during treatment with BLINCYTO®. Your health care provider may temporarily or completely stop your treatment with BLINCYTO® if you have severe side effects.

# Your goal and BLINCYTO®



The good news is that now there is a treatment for detectable traces of disease. BLINCYTO® is the first and only FDA-approved treatment for people with a certain type of **ALL** who are in **remission** but have detectable traces of cancer after **chemotherapy**. <sup>1,4</sup> Go to page 6 to learn about the results of the clinical study.



#### IMPORTANT SAFETY INFORMATION

#### Who should not receive BLINCYTO®?

• Do not receive BLINCYTO® if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO®.

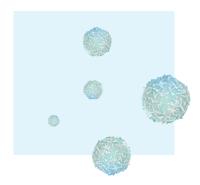
#### What should I avoid while receiving BLINCYTO®?

• Do not drive, operate heavy machinery, or do other dangerous activities while you are receiving BLINCYTO® because BLINCYTO® can cause neurological symptoms such as dizziness, seizures, and confusion.

## What's different about immunotherapy



BLINCYTO® is an **immunotherapy**.<sup>1</sup> It is different from **chemotherapy** because it engages your immune system to find and destroy cancer cells.<sup>5</sup>





#### IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- have a history of neurological problems, such as seizures, confusion, trouble speaking or loss of balance
- have an infection
- have ever had an infusion reaction after receiving  ${\rm BLINCYTO}^{\rm \tiny B}$  or other medications

# BLINCYTO® helped most people become MRD-1,\*

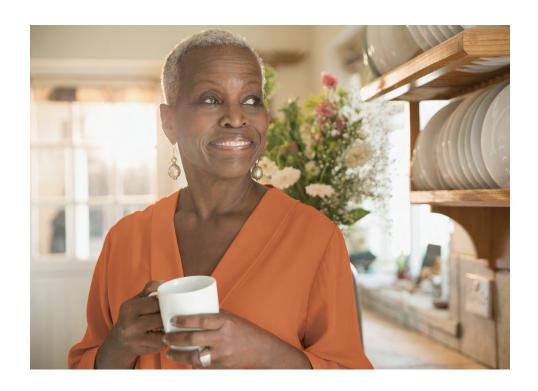


In a study of 86 adults with B-cell precursor **ALL** who tested **MRD+** after **chemotherapy** and were treated with BLINCYTO®



**8 out of 10** (81%) had no detectable cancer after 4 weeks<sup>1,†,‡</sup>

More than half of the people treated with BLINCYTO® were able to get to transplant.<sup>1,§</sup>



#### IMPORTANT SAFFTY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

• have a history of radiation treatment to the brain, or chemotherapy treatment

<sup>\*</sup>As measured by a test that can detect 1 cancer cell out of 10,000 cells in the bone marrow.\(^{1/2}\) (More sensitive testing methods may be able to detect lower levels of cancer cells.)\(^{1/2}\) that is studied had at least 3 rounds of chemotherapy prior to treatment with BLINCYTO\(^{1/2}\). They were in complete remission either for the first or second time. Remission is a response to treatment where signs of cancer have disappeared but does not always mean the cancer is cured.\(^{1/2}\)

<sup>&</sup>lt;sup>†</sup>One cycle of treatment with BLINCYTO® consists of four weeks of treatment followed by two weeks without treatment.¹ §59 out of 86 patients treated with BLINCYTO® in the study proceeded to a transplant.¹

# BLINCYTO® can also help children become MRD-1,4,\*



BLINCYTO® can be used in children, too. It is the first and only treatment of **MRD+** B-cell precursor **ALL** for any age. It is also approved for children whose B-cell precursor ALL has returned or didn't respond to treatment.

Ask your child's doctor about whether BLINCYTO® can help.



\*As measured by a test that can detect 1 cancer cell out of 10,000 cells in the bone marrow. (More sensitive testing methods may be able to detect lower levels of cancer cells).

#### IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- are scheduled to receive a vaccine. You should not receive a "live vaccine" within 2 weeks before you start treatment with BLINCYTO®, during treatment, and until your immune system recovers after you receive your last cycle of BLINCYTO®. If you are not sure about the type of vaccine, ask your health care provider.
- are pregnant or plan to become pregnant. BLINCYTO® may harm your unborn baby. Tell your health care provider if you become pregnant during treatment with BLINCYTO®.

## How you'll receive BLINCYTO®



BLINCYTO® is given by an **intravenous (IV) infusion** into your vein. Dosing of BLINCYTO® occurs in cycles. One cycle is 4 weeks of infusion followed by 2 weeks without infusion.<sup>1</sup>

Your first BLINCYTO® dosing cycle<sup>1,\*</sup>



In the study of BLINCYTO®, most people got 1 or 2 cycles.<sup>6</sup> Your doctor will decide how long you will need to stay on treatment.



\*The time intervals for receiving your BLINCYTO® doses are 24 hours, 48 hours, or 7 days. Your doctor may customize your dosing intervals, dosing cycle, and time-off cycle to meet your needs.¹

#### IMPORTANT SAFFTY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- o If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with BLINCYTO®.
- Females who are able to become pregnant should use an effective form of birth control during treatment with BLINCYTO®, and for 48 hours after the last dose of BLINCYTO®.

## Preparing for and getting treatment



2–3 days in hospital





BLINCYTO® treatment starts in the hospital to monitor and treat you for any serious reactions to the medicine. You will also be given a medicine to help reduce the likelihood of **infusion** reactions.<sup>1,7</sup>

A hospital stay of 3 days is recommended for the first cycle. For the second cycle, a stay of 2 days is recommended.¹ After these stays, your doctor will help you decide when you can go home. You will continue BLINCYTO® with a small portable pump.¹ The medicine will need to be refilled every 1–7 days by a health care professional.¹ Call your health care provider right away if you have any problems with your pump or the alarm sounds.



#### IMPORTANT SAFFTY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- are breastfeeding or plan to breastfeed. It is not known if BLINCYTO® passes into your breast milk. You should not breastfeed during treatment with BLINCYTO® and for 48 hours after your last treatment.
- Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

# Receiving BLINCYTO® at home



You got the good news that you can go home. If your doctor decides you're ready to go home with BLINCYTO®:

- Talk to your health care provider about whether your
   IV bag will be changed at an outpatient center or by your home health care provider
- Call your doctor if you experience any problems or side effects
- Do not change the settings on your pump, even if the alarm sounds. Any setting changes may cause a dose error
- If you are having any problems with your pump, or pump alarm sounds, contact your health care provider immediately
- Keep BLINCYTO® and all medicines out of the reach of other children in the household



#### IMPORTANT SAFETY INFORMATION

#### BLINCYTO® may cause serious side effects, including:

• Infections. BLINCYTO® may cause life-threatening infections that may lead to death. Tell your health care provider right away in case you develop any signs or symptoms of an infection.

## Possible side effects<sup>7</sup>



BLINCYTO® may cause serious side effects that can be severe, life-threatening, or may even lead to death. These include: cytokine release syndrome (CRS), infusion reactions, and neurologic problems.

Symptoms of CRS and infusion reactions may include:

- Fever
- Tiredness or weakness
- Dizziness
- Headache
- Low blood pressure
- Nausea
- Vomiting
- Chills
- Face swelling
- Wheezing or trouble breathing
- Skin rash

Symptoms of neurologic problems include:

- Seizures
- Difficulty in speaking or slurred speech
- Loss of consciousness
- Trouble sleeping
- Confusion and disorientation
- Loss of balance
- Headache
- Difficulty with facial movements, hearing, vision, or swallowing

Tell your health care provider if you have any side effects that bother you or do not go away. These are not all the possible side effects of BLINCYTO®.

#### The most common side effects of BLINCYTO® include:

- Infections
- Fever
- Headache
- Low red blood cell count (anemia)
- Low platelet count (thrombocytopenia)
- Reactions related to infusion of the medicine, such as face swelling, low blood pressure, and high blood pressure (infusion-related reactions)

#### BLINCYTO® may cause the following serious side effects:

- Infections
- Low white blood cell counts (neutropenia)
- Abnormal liver blood test
- Inflammation of the pancreas (pancreatitis)

Tell your health care provider right away if you develop an infection or fever.

## Resources for you



**Doctor discussion guide:** This guide will help you talk to your doctor about BLINCYTO®. It contains a list of FAQs.

**Postdischarge: what you need to know:** Fill out this form when you leave the hospital and continue BLINCYTO® at home. It contains important contacts and additional information.

**Treatment tracker:** This calendar helps you keep track of scheduled appointments and bag changes.

**Medical information card:** Fill out this medical information card. You can keep your important health care contact information in one place here.

Go to **www.blincyto.com/patient/mrd/** to download these helpful tools.



#### IMPORTANT SAFETY INFORMATION

• Low white blood cell counts (neutropenia). Neutropenia is common with BLINCYTO® treatment and may sometimes be life-threatening. Low white blood cell counts can increase your risk of infection. Your health care provider will do blood tests to check your white blood cell counts during treatment with BLINCYTO®. Tell your health care provider right away if you get a fever.

## Support, simplified





#### Referrals to resources for day-to-day living\*

Sometimes you need someone who knows what you're going through. Your Amgen Nurse Ambassador<sup>†</sup> can refer you to independent nonprofit organizations that may provide you with community resources, one-on-one counseling services, and local support groups.

#### Co-pay and reimbursement resources

Whatever type of insurance you have—even if you have none—your Amgen Reimbursement Counselor can help you understand how your Amgen medicine may be covered, and refer you to programs that may be able to help you afford it, such as Amgen FIRST STEP™.

#### **Medication answers**

If you have any questions about your Amgen medicine, your Amgen Nurse Ambassador<sup>†</sup> may help you find the answers.



<sup>\*</sup>Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

<sup>†</sup>Amgen Nurse Ambassadors are only available to patients that are prescribed certain products. Nurse Ambassadors are there to support, not replace, your treatment plan and do not provide medical advice or case management services. You should always consult your healthcare provider regarding medical decisions or treatment concerns.

## Your care team



Health care providers may be only one part of your support network. Your loved ones will be a huge help on your treatment journey.

Friends and family want to be there for you, but may not know how. Let them know it's okay to ask questions and check in with you. And remember, you can ask for help, too. They are there for you.

In addition to your personal caregivers, there are patient support groups that can provide invaluable support throughout the treatment process, such as The Leukemia & Lymphoma Society at **Ils.org**.

You may also want to reach out to the American Cancer Society at **cancer.org**.

Adolescents and young adults may want to check out **stupidcancer.org**.



These third-party resources are for your information only. Amgen does not endorse and is not responsible for the content included in these resources.



### Important safety information

#### INDICATION

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    - **Neurologic problems.** Symptoms of neurologic problems may include: seizures, difficulty in speaking or slurred speech, loss of consciousness, trouble sleeping, confusion and disorientation, loss of balance, headache and difficulty with facial movements, hearing, vision, or swallowing.
  - Your health care provider will check for these problems during treatment with BLINCYTO®. Your health care provider may temporarily or completely stop your treatment with BLINCYTO® if you have severe side effects.

#### Who should not receive BLINCYTO®?

• Do not receive BLINCYTO® if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO®.

#### What should I avoid while receiving BLINCYTO®?

• Do not drive, operate heavy machinery, or do other dangerous activities while you are receiving BLINCYTO® because BLINCYTO® can cause neurological symptoms such as dizziness, seizures, and confusion.

#### Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- have a history of neurological problems, such as seizures, confusion, trouble speaking or loss of balance
- have an infection
- have ever had an infusion reaction after receiving BLINCYTO® or other medications
- have a history of radiation treatment to the brain, or chemotherapy treatment
- are scheduled to receive a vaccine. You should not receive a "live vaccine" within 2 weeks before you start treatment with BLINCYTO®, during treatment, and until your immune system recovers after you receive your last cycle of BLINCYTO®. If you are not sure about the type of vaccine, ask your health care provider.



## Important safety information (cont'd)

- are pregnant or plan to become pregnant. BLINCYTO® may harm your unborn baby. Tell your health care provider if you become pregnant during treatment with BLINCYTO®.
  - o If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with BLINCYTO®.
  - Females who are able to become pregnant should use an effective form of birth control during treatment with BLINCYTO®, and for 48 hours after the last dose of BLINCYTO®.
- are breastfeeding or plan to breastfeed. It is not known if BLINCYTO® passes into your breast milk. You should not breastfeed during treatment with BLINCYTO® and for 48 hours after your last treatment.
- Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- BLINCYTO® may cause serious side effects, including:
  - **Infections.** BLINCYTO® may cause life-threatening infections that may lead to death. Tell your health care provider right away in case you develop any signs or symptoms of an infection.
  - Low white blood cell counts (neutropenia). Neutropenia is common with BLINCYTO® treatment and may sometimes be life-threatening. Low white blood cell counts can increase your risk of infection. Your health care provider will do blood tests to check your white blood cell counts during treatment with BLINCYTO®. Tell your health care provider right away if you get a fever.
  - **Abnormal liver blood test.** Your health care provider will do blood tests to check your liver before you start BLINCYTO® and during treatment with BLINCYTO®.
  - Inflammation of the pancreas (pancreatitis). Pancreatitis may happen in patients treated with BLINCYTO® and corticosteroids. It may be severe and lead to death. Tell your health care provider right away if you have severe abdominal pain that does not go away. The pain may happen with or without nausea and vomiting.
- Your health care provider will do blood tests during treatment to check for side effects.
- The most common side effects of BLINCYTO® include:
  - Infections
  - Fever
  - Headache
  - Low red blood cell count (anemia)
- Low white blood cell count (neutropenia)
- Low white blood cell count with fever (febrile neutropenia)
- Low platelet count (thrombocytopenia)
- Reactions related to infusion of the medicine such as face swelling, low blood pressure, and high blood pressure (infusion-related reactions)

- These are not all the possible side effects of BLINCYTO®.
- Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
- Please read the full Prescribing Information, including **BOXED WARNINGS** and Medication Guide, before you or your child receives BLINCYTO® and before each BLINCYTO® infusion and discuss it with your doctor or visit Blincyto.com.

### Glossary<sup>2,5,8</sup>



**Acute lymphoblastic leukemia (ALL):** A blood cancer in which the bone marrow makes too many lymphoblasts—a certain type of white blood cell.

**Chemotherapy:** A treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. It is often called "chemo."

**Immunotherapy:** A type of medicine that uses your body's own immune system to help fight conditions such as cancer.

**Infusion:** A method of putting fluids, including drugs, into the bloodstream. It is also called "intravenous infusion."

**IV** (intravenous): A way of giving a drug through a needle into a vein.

**Minimal residual disease (MRD):** A relatively small number of cancer cells that remain in the body after treatment and that cannot be detected by standard diagnostic techniques.

**MRD+:** A test result that showed small amounts of cancer after you have completed treatment.

**MRD-:** A test result that found no detectable cancer cells after you have completed treatment.

**Relapse:** The return of a disease or the signs and symptoms of a disease after a period of improvement.

**Remission:** A response to treatment where signs of cancer have disappeared. This does not always mean the cancer has been cured.

References: 1. BLINCYTO® (blinatumomab) prescribing information, Amgen. 2. Brüggemann M, Gökbuget N, Kneba M. Acute lymphoblastic leukemia: monitoring minimal residual disease as a therapeutic principle. Semin Oncol. 2012;39:47-57. 3. Berry DA, Zhou S, Higley H, et al. Association of minimal residual disease with clinical outcome in pediatric and adult acute lymphoblastic leukemia: a meta-analysis. JAMA Oncol. 2017;3:e170580. 4. Food and Drug Administration. FDA expands approval of Blincyto for treatment of a type of leukemia in patients who have a certain risk factor for relapse. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm603151.htm. Accessed April 5, 2018. 5. National Cancer Institute. NCI Dictionary of Cancer Terms. https://www.cancer.gov/publications/dictionaries/cancer-terms. Accessed April 5, 2018. 6. Gökbuget N, Dombret H, Bonifacio M, et al. Blinatumomab for minimal residual disease in adults with B-cell precursor acute lymphoblastic leukemia. Blood. 2018;131:1522-1531. 7. BLINCYTO® (blinatumomab) medication guide, Amgen. 8. Campana D. Minimal residual disease in acute lymphoblastic leukemia. Semin Hematol. 2009;46:100-106.

Please click here to see full Prescribing Information, including Boxed WARNINGS and Medication Guide, for BLINCYTO®.



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