

When you have received at least 1 prior medicine to treat your multiple myeloma,

Discover

WHAT'S POSSIBLE

What is DARZALEX®?

DARZALEX® is a prescription medicine used to treat multiple myeloma:

- In combination with the medicines lenalidomide and dexamethasone **or** bortezomib and dexamethasone, in people who have received at least one prior medicine to treat multiple myeloma
- Alone in people who have received at least three prior medicines to treat multiple myeloma, including a proteasome inhibitor and an immunomodulatory agent, **or** did not respond to a proteasome inhibitor and an immunomodulatory agent

It is not known if DARZALEX® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

DARZALEX® may cause serious reactions including:

- Infusion reactions
- Decreases in blood cell counts
- Changes in blood tests

The most common side effects of DARZALEX® include:

- tiredness
- fever
- cold-like symptoms (upper respiratory infection)
- nerve damage causing tingling, numbness or pain
- nausea
- cough
- swollen hands, ankles or feet
- diarrhea
- muscle spasms
- back pain
- shortness of breath

Please see Important Safety Information on pages 10–11 and Important Product Information in pocket.

 **DARZALEX®**
(daratumumab)
injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL

Your JOURNEY

You are unique, and your experience will be unique.

Decisions and challenges are on the horizon as you continue your journey, and it's important to remember that you and your healthcare team share one goal—

to treat your disease the way that's best for you.

This brochure will help you learn more about DARZALEX[®], a treatment that you and your healthcare team may choose to use during your treatment journey.

Definitions of **bolded** terms throughout this brochure can be found in the glossary on page 15.

Important Safety Information


DARZALEX[®] may cause serious reactions including:

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- Changes in blood tests

The most common side effects of DARZALEX[®] include:

- tiredness
- cough
- nerve damage causing tingling, numbness or pain
- nausea
- muscle spasms
- swollen hands, ankles or feet
- diarrhea
- back pain
- cold-like symptoms (upper respiratory infection)
- shortness of breath
- fever

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100 mg/5 mL, 400 mg/20 mL

What is DARZALEX®?

DARZALEX® (daratumumab) is a treatment used to treat a type of cancer called **multiple myeloma** as:

- part of a **combination therapy** in combination with Revlimid® (lenalidomide) and dexamethasone or Velcade® (bortezomib) and dexamethasone if you have received at least 1 prior medicine
- a **monotherapy** if you have received at least 3 prior medicines, including an **immunomodulatory agent**, such as Revlimid®, and a **proteasome inhibitor (PI)**, such as Velcade®, or if you did not respond to a PI and an immunomodulatory agent

If your doctor is discussing treatment with DARZALEX® in combination with:

- Revlimid® (lenalidomide) and dexamethasone, please turn to page 4
- Velcade® (bortezomib) and dexamethasone, please turn to page 5

If your doctor is discussing treatment with DARZALEX® alone, please turn to page 6

Revlimid® is a registered trademark of Celgene Corporation.
Velcade® is a registered trademark of Millennium Pharmaceuticals, Inc.

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The most common side effects of DARZALEX® include:

- tiredness
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- nerve damage causing tingling, numbness or pain
- nausea
- muscle spasms
- swollen hands, ankles or feet
- diarrhea
- back pain
- cold-like symptoms (upper respiratory infection)
- shortness of breath
- fever

DARZALEX® is a CD38-targeted monoclonal antibody


DARZALEX® is *not* **chemotherapy**. DARZALEX® is a **monoclonal antibody** that works in several ways. One way this monoclonal antibody works is by attaching itself to multiple myeloma cells in your body and directly killing them, and/or allowing your **immune system** to destroy them.

DARZALEX® targets and attaches to a **protein** called **CD38**, which is present on the surface of certain types of cells (eg, red blood cells) and is also present in high numbers on multiple myeloma cells. Since DARZALEX® targets the CD38 protein, it may also affect other cells with this protein on their surface.

How will I receive DARZALEX®?

- DARZALEX® may be given alone or together with other medicines used to treat multiple myeloma
- DARZALEX® will be given to you by **intravenous (IV) infusion** into your vein
- Your healthcare professional will decide the time between doses as well as how many treatments you will receive
- Your healthcare professional will give you medicines before and after each dose of DARZALEX® to help reduce the risk of **infusion reactions**
- If you miss any appointments, call your healthcare professional as soon as possible to reschedule your appointment

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DARZALEX® (daratumumab) studied in combination with Revlimid® (lenalidomide) + dexamethasone

DARZALEX® was studied in combination with Revlimid® + dexamethasone (Rd) vs Rd alone in 569 patients who had received a minimum of 1 prior medicine for their **multiple myeloma**.

The main goal of the study was to measure the length of time patients lived without their multiple myeloma getting worse or their passing away from any cause.

Another goal was to measure overall response rate, which is the percentage of patients who responded to treatment.

Talk to your doctor about how **response** is measured.

Clinical trial results: DARZALEX® + Rd vs Rd alone

More patients responded to DARZALEX® in combination with Rd vs Rd alone



9 out of 10 Patients responded to DARZALEX® + Revlimid® + dexamethasone

vs **7 out of 10** patients with Revlimid® + dexamethasone

DARZALEX® in combination with Rd increased the time patients lived without their multiple myeloma getting worse or their passing away from any cause

- 63% less risk of **disease progression** or passing away with DARZALEX® in combination with Rd vs Rd alone

Important Safety Information

DARZALEX® may cause serious reactions including:

- Infusion reactions
- Decreases in blood cell counts
- Changes in blood tests

The most common side effects of DARZALEX® include:

- tiredness
- cough
- nerve damage causing tingling, numbness or pain
- nausea
- muscle spasms
- swollen hands, ankles or feet
- diarrhea
- back pain
- shortness of breath
- cold-like symptoms (upper respiratory infection)
- fever

DARZALEX® (daratumumab) studied in combination with Velcade® (bortezomib) + dexamethasone

DARZALEX® was studied in combination with Velcade® + dexamethasone (Vd) vs Vd alone in 498 patients who had received a minimum of 1 prior medicine for their **multiple myeloma**.

The main goal of the study was to measure the length of time patients lived without their multiple myeloma getting worse or their passing away from any cause.

Another goal was to measure overall response rate, which is the percentage of patients who responded to treatment.

Talk to your doctor about how **response** is measured.

Clinical trial results: DARZALEX® + Vd vs Vd alone

More patients responded to DARZALEX® in combination with Vd than to Vd alone



responded to DARZALEX® + Velcade® + dexamethasone

vs almost 6 out of 10 patients with Velcade® + dexamethasone

DARZALEX® in combination with Vd increased the time patients lived without their multiple myeloma getting worse or their passing away from any cause

- 61% less risk of **disease progression** or passing away with DARZALEX® + Vd vs Vd alone

Important Safety Information

DARZALEX® may cause serious reactions including:

- Infusion reactions
- Decreases in blood cell counts
- Changes in blood tests

The most common side effects of DARZALEX® include:

- tiredness
- cough
- nerve damage causing tingling, numbness or pain
- nausea
- muscle spasms
- swollen hands, ankles or feet
- diarrhea
- back pain
- shortness of breath
- cold-like symptoms (upper respiratory infection)
- fever

DARZALEX® (daratumumab) studied as a monotherapy

DARZALEX® was studied as a **monotherapy** in 106 patients who had received at least 3 prior medicines to treat their **multiple myeloma**, including a **proteasome inhibitor (PI)** and an **immunomodulatory agent**, or did not respond to a PI and an immunomodulatory agent. Patients had received a **median** of 5 prior lines of therapy.

The main goal of the study was to measure overall response rate. Overall response rate is the percentage of patients who responded to treatment.

Talk to your doctor about how **response** is measured.

Clinical trial results: DARZALEX® as a monotherapy

When these patients were treated with DARZALEX®, 29% responded

- This response lasted for a median duration of 7.4 months

Of patients who responded, response was seen between 0.9 and 5.6 months



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DARZALEX® may cause serious reactions including:

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- Decreases in blood cell counts
- Changes in blood tests

The most common side effects of DARZALEX® include:

- tiredness
- cough
- nerve damage causing tingling, numbness or pain
- nausea
- muscle spasms
- swollen hands, ankles or feet
- diarrhea
- back pain
- shortness of breath
- cold-like symptoms (upper respiratory infection)
- fever



What can I expect before treatment?

Your healthcare professional will do blood tests to match your blood type before you start treatment with DARZALEX®.

Your healthcare professional will give you medicines before each dose of DARZALEX® to help reduce the risk of **infusion reactions**.

These include:

- Medicines to prevent an allergic reaction (antihistamines)
- Medicines to prevent inflammation (corticosteroids)
- Medicines to reduce fever, such as acetaminophen (antipyretics)

Please see page 8 to learn more about infusion reactions.

Leading up to your infusion

Make sure you set aside enough time in your day. With that in mind, there are some things you may want to consider:

- Wear comfortable, layered clothing
- Bring drinks and snacks
- Bring headphones, a music player, a tablet, or other activities to pass time
- Make a list of things you need to do and questions to ask your doctor

You have a lot to think about as you get started with your infusions. The maker of DARZALEX® offers tools that can direct you to support services to help you during your journey. Visit www.darzalex.com to download these tools and sign up for Janssen CarePath for DARZALEX®.

Continue


Important Safety Information

- **Changes in blood tests.** DARZALEX® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX®. **Tell all of your healthcare providers that you are being treated with DARZALEX® before receiving blood transfusions.**

Important Safety Information

- **Decreases in blood cell counts.** DARZALEX® can decrease white blood cell counts which help fight infections and blood cells called platelets which help to clot blood. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

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What can I expect during treatment?

During your infusion, stay mindful of how you feel

It's important to tell your healthcare professional right away if you get any of the symptoms listed below, which could mean you are having an infusion reaction.

Infusion reaction symptoms may include:

- shortness of breath or trouble breathing
- dizziness or lightheadedness (hypotension)
- cough
- wheezing
- throat tightness
- runny or stuffy nose
- headache
- itching
- nausea
- vomiting
- chills
- fever

A healthcare professional will monitor you during your DARZALEX® infusion. If you do have an infusion reaction, your healthcare professional may temporarily stop your infusion or completely stop treatment with DARZALEX®.

The first infusion of DARZALEX® may take about 7 hours. Future infusions will take less time but may still take 3 to 5 hours.

Infusion reactions are common with DARZALEX® and can be severe.

Almost half (47%) of patients treated with DARZALEX® in clinical trials experienced an infusion reaction. Infusion reactions can occur with the first infusion (46%), the second infusion (2%), and subsequent infusions (4%). These reactions are most likely to happen during the first infusion and are less likely to happen with future infusions.

The most common side effects of DARZALEX® include

tiredness, nausea, diarrhea, shortness of breath, fever, cough, muscle spasms, back pain, cold-like symptoms (upper respiratory infection), nerve damage causing tingling, numbness, or pain, and swollen hands, ankles, or feet.

Continue



What can I expect after treatment?

Post-infusion medications

You will be given medicines (corticosteroids) by mouth to lower the chance of delayed infusion reactions. In addition, if you have a history of breathing problems, such as chronic obstructive pulmonary disease, you may be given additional medications that may help prevent these problems, such as bronchodilators or inhaled corticosteroids.

Changes in blood tests

DARZALEX® can affect blood test results used to match your blood for transfusions. These changes can last for up to 6 months after your final dose of DARZALEX®. **Tell all of your healthcare professionals that you are being treated with DARZALEX® before receiving blood transfusions.**

Decreases in blood cell counts

DARZALEX® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Tell your healthcare professionals if you develop fever or have signs of bruising or bleeding.

Be sure to discuss with your healthcare professional any side effects you may experience.

Questions for your healthcare team

- What treatment option is right for me?
- What are the goals of this treatment?
- How is DARZALEX® different from my last treatment?
- How will I know if my treatment is working?
- How will you monitor my treatment results?
- What do I need to know about my treatment schedule?
- What side effects could I expect with treatment?



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Important Safety Information

What should I tell my healthcare provider before taking DARZALEX®?

Before you receive DARZALEX®, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of breathing problems
- have had shingles (herpes zoster)
- are pregnant or plan to become pregnant.
—Females who are able to become pregnant should use an effective method of birth control during treatment and for at least 3 months after your final dose of DARZALEX®. Talk to your healthcare provider about birth control methods that you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if DARZALEX® passes into your breast milk.

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

How will I receive DARZALEX®?

- DARZALEX® may be given alone or together with other medicines used to treat multiple myeloma.
- DARZALEX® will be given to you by intravenous (IV) infusion into your vein.

- Your healthcare provider will decide the time between doses as well as how many treatments you will receive.
- Your healthcare provider will give you medicines before each dose of DARZALEX® and on the first day after each dose of DARZALEX® to help reduce the risk of infusion reactions.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment

What are the possible side effects of DARZALEX®?

DARZALEX® may cause serious reactions, including:

- **Infusion reactions.** Infusion reactions are common with DARZALEX® and can be severe. Your healthcare provider may temporarily stop your infusion or completely stop treatment with DARZALEX® if you have infusion reactions. Tell your healthcare provider right away if you get any of the following symptoms:
 - shortness of breath or trouble breathing
 - dizziness or lightheadedness (hypotension)
 - cough
 - wheezing
 - throat tightness
 - runny or stuffy nose
 - headache
 - itching
 - nausea
 - vomiting
 - chills
 - fever

Important Safety Information (cont'd)

- **Changes in blood tests.** DARZALEX® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX®. **Tell all of your healthcare providers that you are being treated with DARZALEX® before receiving blood transfusions.**
- **Decreases in blood cell counts.** DARZALEX® can decrease white blood cell counts which help fight infections and blood cells called platelets which help to clot blood. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

The most common side effects of DARZALEX® include:

- tiredness
- muscle spasms
- nausea
- back pain
- diarrhea
- cold-like symptoms
(upper respiratory infection)
- shortness of breath
- nerve damage causing
tingling, numbness or pain
- fever
- swollen hands, ankles or feet
- cough

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DARZALEX®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of DARZALEX®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider or pharmacist for information about DARZALEX® that is written for health professionals.

063321-161115

Janssen CarePath

Get support on your treatment path

Janssen CarePath is here to help answer your questions about treatment with DARZALEX[®]. Once your doctor has prescribed DARZALEX[®], we will provide you with educational information and resources that may help you get started and stay on track. We'll also give you information about how to pay for your treatment, how this medication is given by your doctor, and what questions you may want to ask your doctor and insurance carrier.

Knowing that you may have questions, a Janssen CarePath Care Coordinator is available to offer one-on-one personalized assistance with:

▶ **Paying for DARZALEX[®]:** Identifying cost support options that may help with managing your out-of-pocket costs for DARZALEX[®]—whether you have commercial or private health insurance, government insurance such as Medicare or Medicaid, or have no insurance coverage.

▶ **Getting started:** A personally assigned Janssen CarePath Care Coordinator will work closely with you and your doctor to help you get started by:

- Reviewing your health plan benefits to help answer questions you may have about insurance coverage for DARZALEX[®]
- Identifying options that may help make DARZALEX[®] more affordable, if needed
- Providing transportation assistance information and referral to independent organizations that may provide assistance with costs associated with travel to and from treatment
- Offering treatment education resources such as the DARZALEX[®] Comfort Kit
- Connecting you with a clinical nurse to answer questions about your disease and treatment with DARZALEX[®]*

▶ **Staying on track:** Janssen CarePath offers additional support to help keep you informed about DARZALEX[®] and provides ongoing resources and services to help you stay on track with your DARZALEX[®] treatment as prescribed by your doctor. We offer:

- Ongoing e-mails and phone calls as requested from a clinical nurse throughout your journey
- Personalized, live appointment reminder calls
- Downloadable tools
- Mindfulness exercises and techniques to help you cope with stress
- Tools to help you make healthy lifestyle choices
- Information about the Advocacy Connector, a website that connects patients and caregivers to national and/or state advocacy groups that offer resources relevant to their needs. Visit advocacyconnector.com

Now that you have begun the journey with your DARZALEX[®] infusion treatment, please know that we are here to help.

Contact Janssen CarePath to get help today.

Call: 1-844-55DARZA (1-844-553-2792)

Monday–Friday, 8 AM–8 PM ET

Go online: JanssenCarePath.com/DARZALEX

*The DARZALEX[®] nurse program is not intended to provide medical advice, replace your treatment plan with your doctor or nurse, or provide treatment or case management services. You should always talk to your healthcare provider and treatment team about any medical decisions and concerns you may have.

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Affordability options for DARZALEX[®] (daratumumab)

Once your doctor has prescribed DARZALEX[®], Janssen CarePath can help you find the resources you may need to help you get started on your medication and stay on track. You may have options that may make your treatment more affordable.

For more information, visit [JanssenCarePath.com/DARZALEX](https://www.JanssenCarePath.com/DARZALEX) or call your dedicated Care Coordinator at 1-844-55DARZA (1-844-553-2792), Monday–Friday, 8 AM–8 PM ET.

▶ If you use commercial or private health insurance to pay for your medication

Eligible patients pay no more than \$10 per infusion*

Infusions 1–8: Pay only \$5

Infusions 9+: Pay only \$10

*\$15,000 maximum program benefit per calendar year. **Not valid for patients using Medicare or Medicaid.** Eligibility requirements apply.

To determine eligibility, enroll and activate, or get a savings card, visit [CarePathSavingsProgram.com](https://www.CarePathSavingsProgram.com) or call 1-844-55DARZA (1-844-553-2792).

Once you are enrolled in the program, before the calendar year ends, you will receive information and eligibility requirements for continued participation in the program.

▶ If you use Medicare

Janssen CarePath can refer you to the Medicare Savings Program to discuss eligibility and program benefits.

To learn more about eligibility and how the Medicare Savings Program can help you pay for Medicare Part B products, visit [medicare.gov/contacts/#resources/msps](https://www.medicare.gov/contacts/#resources/msps) and select the appropriate state.

Continue ▶

The Janssen CarePath Savings Program for DARZALEX[®] Visa[®] Prepaid Card is issued by Republic Bank & Trust Company, member FDIC, pursuant to a license from Visa U.S.A. Inc.



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Affordability options for DARZALEX[®] (daratumumab) (cont'd)

- ▶ If you use government-funded insurance such as Medicare or Medicaid, or need supplemental assistance with paying for your medication

Independent foundation support may be available:

- Good Days
www.mygooddays.org | 1-877-968-7233
- CancerCare[®]
www.cancercares.org | 1-800-813-4673
- Patient Access Network Foundation
www.panfoundation.org | 1-866-316-7263
- Patient Advocate Foundation
www.patientadvocate.org | 1-800-532-5274
- Leukemia & Lymphoma Society
www.lls.org | 1-877-557-2672

Independent co-pay assistance foundations have their own rules for eligibility. We cannot guarantee a foundation will help you. We only can refer you to a foundation that supports your disease state. This information is provided as a resource for you. We do not endorse or show financial preference for any particular foundation. The foundations on this list are not the only ones that might be able to help you.

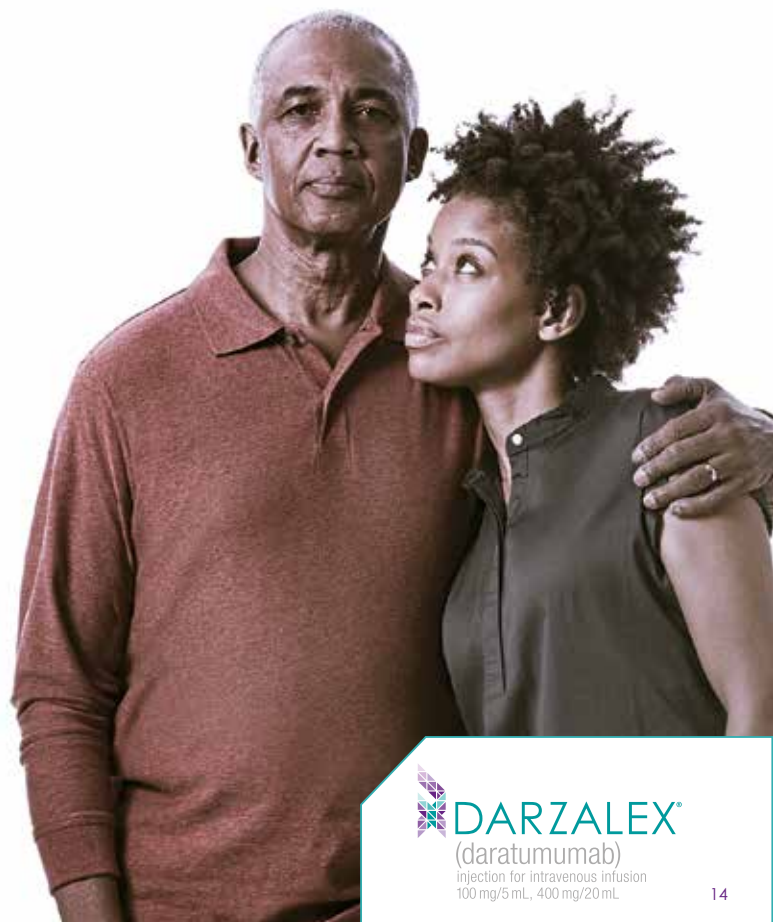
- ▶ If you have no health insurance or no coverage

JanssenPrescriptionAssistance.com provides information on affordability programs that may be available. For a comprehensive list of affordability programs, visit JanssenPrescriptionAssistance.com/DARZALEX.

CancerCare[®] is a registered trademark of CancerCare, Inc.

Other resources

Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF) provides free prescription medications to eligible individuals who do not have insurance coverage for their medications and do not have adequate financial resources to pay for them. Please contact a JJPAF program specialist at 1-800-652-6227 (9 AM to 6 PM ET) or visit the foundation website at JJPAF.org to see if you might qualify for assistance.



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Glossary of terms

CD38—A protein found on the surface of cells and in high numbers on myeloma cells.

Chemotherapy—A chemical drug that stops the growth of cancer cells, either by killing them or by stopping them from dividing. Chemotherapy may be given by mouth, injection, or infusion, or on the skin, depending on the type and stage of the cancer being treated. It may be given alone or with other treatments, such as surgery, radiation therapy, or biologic therapy.

Combination therapy—Use of more than one treatment to treat a certain disease or condition.

Disease progression—Cancer continuing to grow or spread.

Immune system—Several types of cells and organs that work together to help the body fight infections and other diseases.

Immunomodulatory agents—Drugs such as Revlimid® (lenalidomide) that change a patient's immune response by enhancing or suppressing the immune system.

Infusion reaction—A side effect seen with some drugs that are given intravenously.

Intravenous (IV) infusion—A way of giving medicines or other fluids by inserting them into the bloodstream through a needle or tube in a vein.

Median—The middle number in an ordered set of values arranged from smallest to largest. Example: 3, 5, 12. The median is 5.

Monoclonal antibody—A man-made molecule that binds to substances in the body, including cancer cells. Monoclonal antibodies work with your immune system.

Monotherapy—Use of one type of treatment to treat a certain disease or condition.

Multiple myeloma—A type of cancer formed by malignant plasma cells. Plasma cells are found in the bone marrow.

Proteasome inhibitors (PIs)—Drugs such as Velcade® (bortezomib) that slow down cancer cell growth by interfering with processes that play a role in cell function.

Protein—Molecule made up of amino acids and needed for the body to function properly. Proteins are the basis of skin, hair, and other substances in the body.


Response—A measurement taken after treatment that shows a decrease in the amount of myeloma cells in the bone marrow. Response can be measured as partial or complete response.

For more information,
visit www.darzalex.com.

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janssen  Oncology

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