FIRST AND ONLY

DARZALEX *FASPRO*® is now approved as the first and only therapy for use alone to treat adults with high-risk smoldering multiple myeloma (an early form of multiple myeloma that has a higher chance of progressing to active multiple myeloma)

What is high-risk smoldering multiple myeloma?

Smoldering multiple myeloma is an asymptomatic stage of disease that has the potential to progress to active multiple myeloma. **Some people with smoldering multiple myeloma are more likely to develop active myeloma than others; this is referred to as high-risk smoldering multiple myeloma.**

According to a study done by the Mayo clinic, ~47% of people with high-risk smoldering multiple myeloma progressed to having active multiple myeloma within 2 years

If you have high-risk smoldering multiple myeloma, talk to your doctor about how getting treatment could potentially slow or delay progression to active multiple myeloma.

What is DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)?

DARZALEX *FASPRO*® is a prescription medicine used alone to treat adults with high-risk smoldering multiple myeloma (an early form of multiple myeloma that has a higher chance of progressing to active multiple myeloma).

SELECT IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX *FASPRO*® if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX *FASPRO*®. See **page 5** for a complete list of ingredients in DARZALEX *FASPRO*®

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

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX *FASPRO*® could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX *FASPRO*®. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.
- are pregnant or plan to become pregnant. DARZALEX *FASPRO*® may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX *FASPRO*®.
  - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX *FASPRO*®. Talk to your healthcare provider about birth control methods that you can use during this time.
  - Before starting DARZALEX *FASPRO*® in combination with lenalidomide, thalidomide, or pomalidomide, females and males must agree to the instructions in the lenalidomide, thalidomide, or pomalidomide REMS program.

A clinical study compared the outcomes for people treated with DARZALEX *FASPRO*® vs those who were only monitored for disease progression without active treatment

A phase 3 clinical study evaluated 390 people who were diagnosed with high-risk smoldering multiple myeloma.

- The median age of people in the study was 64 years
- The clinical study's primary goal was to evaluate how long people lived without progressing to active multiple myeloma or passing away
- **DARZALEX *FASPRO*® is only indicated for people with high-risk smoldering multiple myeloma. It is not indicated for other risk categories**

Talk to your doctor about DARZALEX *FASPRO*® if you have been diagnosed with high-risk smoldering multiple myeloma

People who were treated with DARZALEX *FASPRO*® had a better chance of living longer without their disease progressing to active multiple myeloma or passing away. This is called progression-free survival.

After 60 months, **about 63% of people who were diagnosed with high-risk smoldering multiple myeloma and were treated with DARZALEX *FASPRO*® had not progressed to active multiple myeloma or passed away**, while about 41% of people who were only monitored for disease progression without active treatment had still not progressed to active multiple myeloma or passed away.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX *FASPRO*® may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX *FASPRO*®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX *FASPRO*® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX *FASPRO*®.
  - shortness of breath or trouble breathing
  - dizziness or lightheadedness (hypotension)
  - cough
  - wheezing
  - heart beating faster than usual
  - low oxygen in the blood (hypoxia)
  - throat tightness or irritation
  - runny or stuffy nose
  - headache
  - itching
  - high blood pressure
  - eye pain
  - fever
  - chest pain
  - blurred vision
  - nausea
  - vomiting
  - chills

Indications and Important Safety Information for DARZALEX *FASPRO*®

What is DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)?

DARZALEX *FASPRO*® is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, lenalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines lenalidomide and dexamethasone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant) and in people whose multiple myeloma has come back or did not respond to treatment who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines bortezomib, thalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines bortezomib and dexamethasone in people who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines pomalidomide and dexamethasone in people who have received at least one prior medicine, including lenalidomide and a proteasome inhibitor, to treat multiple myeloma
- in combination with the medicines carfilzomib and dexamethasone in people whose multiple myeloma has come back or did not respond to treatment who have received one to three prior medicines to treat multiple myeloma
- alone in people who have received at least three prior medicines, including a proteasome inhibitor and an immunomodulatory agent, **or** did not respond to a proteasome inhibitor and an immunomodulatory agent

DARZALEX *FASPRO*® is a prescription medicine used alone to treat adults with high-risk smoldering multiple myeloma (an early form of multiple myeloma that has a higher chance of progressing to active multiple myeloma).

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

IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX *FASPRO*® if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX *FASPRO*®. See below for a complete list of ingredients in DARZALEX *FASPRO*®.

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

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX *FASPRO*® could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX *FASPRO*®. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.
- are pregnant or plan to become pregnant. DARZALEX *FASPRO*® may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX *FASPRO*®.

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Indications and Important Safety Information for DARZALEX *FASPRO*® (cont)

- Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX *FASPRO*®. Talk to your healthcare provider about birth control methods that you can use during this time.
- Before starting DARZALEX *FASPRO*® in combination with lenalidomide, thalidomide, or pomalidomide, females and males must agree to the instructions in the lenalidomide, thalidomide, or pomalidomide REMS program.
  - The lenalidomide, thalidomide, and pomalidomide REMS have more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant.
  - For males who have female partners who can become pregnant, there is information in the lenalidomide, thalidomide, and pomalidomide REMS about sperm donation and how lenalidomide, thalidomide, and pomalidomide can pass into human semen.

- are breastfeeding or plan to breastfeed. It is not known if DARZALEX *FASPRO*® passes into your breast milk. You should not breastfeed during treatment with DARZALEX *FASPRO*®. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX *FASPRO*®.

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 *FASPRO*®?

- DARZALEX *FASPRO*® may be given alone to treat multiple myeloma or high-risk smoldering multiple myeloma, or together with other medicines used to treat multiple myeloma.
- DARZALEX *FASPRO*® will be given to you by your healthcare provider as an injection under the skin in the stomach area (abdomen).
- DARZALEX *FASPRO*® is injected over 3 to 5 minutes.
- 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 *FASPRO*® and after each dose of DARZALEX *FASPRO*® to help reduce the risk of serious allergic reactions and other reactions due to release of certain substances by your body (systemic).

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

DARZALEX *FASPRO*® may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions**. Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX *FASPRO*®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX *FASPRO*® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX *FASPRO*®.
  - shortness of breath or trouble breathing
  - dizziness or lightheadedness (hypotension)
  - cough
  - wheezing
  - heart beating faster than usual
  - low oxygen in the blood (hypoxia)
  - throat tightness or irritation
  - runny or stuffy nose
  - headache
  - itching
  - high blood pressure
  - eye pain
  - fever
  - chest pain
  - blurred vision
  - nausea
  - vomiting
  - chills
- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX *FASPRO*®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX *FASPRO*®.

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Indications and Important Safety Information for DARZALEX *FASPRO*® (cont)

- **Infections.** DARZALEX *FASPRO*® can cause serious life-threatening infections that can lead to death. Tell your healthcare provider right away if you develop a fever, trouble breathing, cough, burning or pain when you urinate, or any other signs and symptoms of infection during treatment.
- **Decreases in blood cell counts.** DARZALEX *FASPRO*® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX *FASPRO*® and can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX *FASPRO*®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.
- **Changes in blood tests.** DARZALEX *FASPRO*® 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 *FASPRO*®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX *FASPRO*®. **Tell all of your healthcare providers that you are being treated with DARZALEX *FASPRO*® before receiving blood transfusions.**

The most common side effects of DARZALEX *FASPRO*® when used alone include:

- cold-like symptoms (upper respiratory tract infection)
- muscle, bone, and joint pain
- tiredness
- diarrhea
- rash
- trouble sleeping, including sleep apnea and restless legs
- nerve problems, including increased or decreased sensitivity to touch, temperature, or pain; loss of smell; and numbness, tingling, or burning sensations
- injection site reactions

The most common side effects of DARZALEX *FASPRO*® when used in combination therapy include:

- tiredness
- nausea
- diarrhea
- shortness of breath
- trouble sleeping
- headache
- rash
- fever
- cough
- muscle spasms
- back pain
- vomiting
- high blood pressure
- muscle, bone, and joint pain
- cold-like symptoms (upper respiratory infection)
- nerve damage causing tingling, numbness, or pain
- constipation
- lung infection (pneumonia)
- swollen hands, ankles, or feet
- decreased red blood cell counts

The most common severe abnormal blood test results with DARZALEX *FASPRO*® include decreased white blood cells, platelets, and red blood cells

These are not all of the possible side effects of DARZALEX *FASPRO*®. 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 *FASPRO*®

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

Active ingredient: daratumumab and hyaluronidase-fihj

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 20, sorbitol, water for injection

Please click here to read full Prescribing Information for DARZALEX *FASPRO*®.

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