



# You are cordially invited to attend a non-CME educational program TALVEY Overview & DARZALEX FASPRO PERSEUS TRIAL

# **Presented by**

Rhonda Hewitt, NP Adult Nurse Practitioner Stanford Health Care

Speaker is a paid consultant of Johnson & Johnson

Date

daratumumab)

ijection for intravenous infusion 30 mg/5 mL, 400 mg/20 mL

Tuesday, October 15, 2024 at 6:00 PM Pacific Time Tamarine Restaurant 546 University Avenue, Palo Alto, California 94301 (650) 325-8500

Location

We look forward to your participation in this informative discussion. Reserve your spot now by contacting your Johnson & Johnson Representative, Kiffany Licea at klicea@its.jnj.com (831) 392-6205, or visit https://janssenspeakerprograms.my.salesforce-sites.com/Invitation/Register/INT-0021571

In adherence with PhRMA guidelines, spouses or other guests are not permitted to attend company-sponsored programs.

For all attendees, please be advised that information such as your name and the value and purpose of any educational item, meal, or other items of value you receive may be publicly disclosed. If you are licensed in any state or other jurisdiction, or are an employee or contractor of any organization or governmental entity that limits or prohibits meals from pharmaceutical companies, please identify yourself so that you (and we) are able to comply with such requirements.

Please note that the company prohibits the offering of gifts, gratuities, or meals to federal government employees/officials. Thank you for your cooperation.

This promotional educational activity is not accredited. The program content is developed by Janssen Biotech, Inc. Speakers are paid consultants presenting on behalf of the company and are required to present information in compliance with FDA requirements for communications about its medicines.

The personal information you provide may be used to contact you about your request to attend the Janssen Biotech, Inc., educational program using your preferred method of communication as indicated by you. This information may be shared with Janssen Biotech, Inc., its affiliates, and a third party for the sole purpose of completing your registration for this program and as required by law.

# DARZALEX® (daratumumab) and

# DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

INDICATIONS

DARZALEX® is indicated for the treatment of adult patients with multiple myeloma:

 In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy

- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy

DARZALEX FASPRO® is indicated for the treatment of adult patients with multiple myeloma:

 In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant

#### SELECTED IMPORTANT SAFETY INFORMATION

DARZALEX® AND DARZALEX FASPRO®: CONTRAINDICATIONS

DARZALEX<sup>®</sup> and DARZALEX FASPRO<sup>®</sup> are contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase (for DARZALEX FASPRO<sup>®</sup>), or any of the components of the formulations.

Please see the following pages for additional Important Safety Information. Please see accompanying full Prescribing Information for DARZALEX<sup>®</sup> and DARZALEX *FASPRO*<sup>®</sup>.

# TALVEY<sup>®</sup> (talquetamab-tgvs) INDICATION AND USAGE

TALVEY® is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

### IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY, including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TALVEY<sup>®</sup>. Initiate TALVEY<sup>®</sup> treatment with stepup dosing to reduce the risk of CRS. Withhold TALVEY<sup>®</sup> until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY<sup>®</sup>. Monitor patients for signs and symptoms of neurologic toxicity including ICANS

during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY<sup>®</sup> is available only through a restricted program called the TECVAYLI<sup>®</sup> and TALVEY<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS).

Please see the following pages for additional Important Safety Information. Please read accompanying full Prescribing Information, including Boxed WARNING, for TALVEY<sup>®</sup>.

Johnson&Johnson © Janssen Biotech, Inc. 2024 08/24 cp-441456v2

## INDICATIONS (cont.)

 $\mathsf{DARZALEX}^{\otimes}$  (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI)
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI)
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

# IMPORTANT SAFETY INFORMATION (cont.)

## DARZALEX®: Infusion-Related Reactions

DARZALEX<sup>®</sup> can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX<sup>®</sup>. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma.

Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension, and blurred vision.

When DARZALEX<sup>®</sup> dosing was interrupted in the setting of autologous stem cell transplant (ASCT) (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX<sup>®</sup>, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX<sup>®</sup> following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, ie, 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX® infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX® therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX<sup>®</sup> infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with DARZALEX<sup>®</sup> infusion. If ocular symptoms occur, interrupt DARZALEX<sup>®</sup> infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX<sup>®</sup>.

Please see the following pages for additional Important Safety Information. Please see accompanying full Prescribing Information for DARZALEX® and DARZALEX FASPRO®.

# IMPORTANT SAFETY INFORMATION (cont.)

### CONTRAINDICATIONS: None. WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® (talquetamab-tgvs) can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients. Grade 2 in 17%, and Grade 3 in 1.5%. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. Recurrent CRS occurred in 30% of patients. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic Toxicity including ICANS: TALVEY® can cause serious or life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including fatal reactions. In the clinical trial, neurologic toxicity occurred in 55% of patients who received the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction (10%). ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment and treat promptly. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity. Withhold or permanently discontinue TALVEY® based on severity and consider further management per current practice guidelines [see Dosage and Administration (2.5)].

Due to the potential for neurologic toxicity, patients receiving TALVEY® are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during the step-up dosing schedule and for 48 hours after completion of the step-up dosing schedule, and in the event of new onset of any neurological symptoms, until symptoms resolve.

TECVAYLI® and TALVEY® REMS: TALVEY® is available only through a restricted program under a REMS, called the TECVAYLI® and TALVEY® REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Further information about the TECVAYLI<sup>®</sup> and TALVEY<sup>®</sup> REMS program is available at <u>www.TEC-TALREMS.com</u> or by telephone at 1-855-810-8064.

**Oral Toxicity and Weight Loss:** TALVEY<sup>®</sup> can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis. In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

Please see the following page for additional Important Safety Information. Please read accompanying full Prescribing Information, including Boxed WARNING, for TALVEY<sup>®</sup>.

Johnson&Johnson © Janssen Biotech, Inc. 2024 08/24 cp-441456v2

#### IMPORTANT SAFETY INFORMATION (cont.)

#### DARZALEX FASPRO® (daratumumab and hyaluronidase fihj): Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO<sup>®</sup>. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO<sup>®</sup>.

#### Systemic Reactions

In a pooled safety population of 1249 patients with multiple myeloma (N=1056 or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO®* as monotherapy or in combination, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3.2%, Grade 3: 0.7%, Grade 4: 0.1%). Systemic administration-related reactions occurred in 7% of patients with the first injection, 0.2% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 2.9 hours (range: 5 minutes to 3.5 days). Of the 165 systemic administration-related reactions that occurred in 93 patients, 144 (87%) occurred on the day of DARZALEX *FASPRO®* administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen, and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX *FASPRO*<sup>®</sup>. Consider administering corticosteroids and other medications after the administration of DARZALEX *FASPRO*<sup>®</sup> depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX *FASPRO*<sup>®</sup> and seek immediate ophthalmologic evaluation prior to restarting DARZALEX *FASPRO*<sup>®</sup>.

#### Local Reactions

In this pooled safety population, injection-site reactions occurred in 7% of patients, including Grade 2 reactions in 0.8%. The most frequent (>1%) injection-site reaction was injection-site erythema. These local reactions occurred a median of 5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO<sup>®</sup>. Monitor for local reactions and consider symptomatic management.

# DARZALEX® (daratumumab) and DARZALEX FASPRO®: Neutropenia and Thrombocytopenia

DARZALEX<sup>®</sup> and DARZALEX *FASPRO*<sup>®</sup> may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX<sup>®</sup> or DARZALEX *FASPRO*<sup>®</sup> until recovery of neutrophils or for recovery of platelets.

In lower body weight patients receiving DARZALEX FASPRO®, higher rates of Grade 3-4 neutropenia were observed.

#### DARZALEX® and DARZALEX FASPRO®: Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX® and DARZALEX FASPRO®. Type and screen patients prior to starting DARZALEX® and DARZALEX FASPRO®.

# DARZALEX® and DARZALEX FASPRO®: Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Please see the following page for additional Important Safety Information. Please see accompanying full Prescribing Information for DARZALEX® and DARZALEX FASPRO®.

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

#### Oral Toxicity and Weight Loss (cont.)

TALVEY<sup>®</sup> (talquetamab-tgvs) can cause weight loss. In the clinical trial, 62% of patients experienced weight loss of 5% or greater, regardless of having an oral toxicity, including 28% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY® or permanently discontinue based on severity.

Infections: TALVEY® can cause infections, including life-threatening or fatal infections. Serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis and COVID-19 (2.7%).

Monitor patients for signs and symptoms of infection prior to and during treatment with TALVEY® and treat appropriately. Administer prophylactic antimicrobials according to local guidelines. Withhold or consider permanent discontinuation of TALVEY® as recommended, based on severity.

**Cytopenias:** TALVEY<sup>®</sup> can cause cytopenias, including neutropenia and thrombocytopenia. In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY<sup>®</sup>. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY<sup>®</sup> as recommended, based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash. In the clinical trial, skin reactions occurred in 62% of patients, with grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY® as recommended based on severity.

Hepatotoxicity: TALVEY<sup>®</sup> can cause hepatotoxicity. Elevated ALT occurred in 33% of patients, with grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY® or consider permanent discontinuation of TALVEY®, based on severity [see Dosage and Administration (2.5)].

Embryo-Fetal Toxicity: Based on its mechanism of action, TALVEY® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TALVEY® and for 3 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

The most common Grade 3 or 4 laboratory abnormalities (≥30%) are lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

#### Please read accompanying full Prescribing Information, including Boxed WARNING, for TALVEY<sup>®</sup>.

cp-394174v4

## IMPORTANT SAFETY INFORMATION (cont.)

# DARZALEX® (daratumumab) and DARZALEX FASPRO® (daratumumab and hyaluronidase fihj): Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX<sup>®</sup> and DARZALEX FASPRO<sup>®</sup> can cause fetal harm when administered to a pregnant woman. DARZALEX<sup>®</sup> and DARZALEX FASPRO<sup>®</sup> may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX<sup>®</sup> and DARZALEX FASPRO<sup>®</sup> and for 3 months after the last dose.

The combination of DARZALEX® or DARZALEX FASPRO® with lenalidomide, pomalidomide, or thalidomide is contraindicated in pregnant women because lenalidomide, pomalidomide, and thalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, pomalidomide, or thalidomide prescribing information on use during pregnancy.

### DARZALEX®: ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence ≥20%) with DARZALEX<sup>®</sup> were upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX<sup>®</sup> are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

#### DARZALEX FASPRO®: ADVERSE REACTIONS

In multiple myeloma, the most common adverse reaction (≥20%) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, headache, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, peripheral edema, musculoskeletal pain, and rash. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX FASPRO® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please see accompanying full Prescribing Information for DARZALEX<sup>®</sup>. Please see accompanying full Prescribing Information for DARZALEX FASPRO<sup>®</sup>.

cp-248517v5