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For Immediate Release

# DARZALEX® (daratumumab)-based regimens significantly improve clinical outcomes in both transplant-eligible and -ineligible patients who are newly diagnosed with multiple myeloma

*88 percent of transplant-eligible patients achieved a complete response or better, and 47 percent of patients sustained MRD-negativity for longer than one year with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)-based induction, consolidation and maintenance regimens in the Phase 3 PERSEUS study*

*7.5 years median overall survival achieved with DARZALEX®-based regimen in Phase 3 MAIA final analysis is the longest reported in patients ineligible for transplant*

**CHICAGO (June 3, 2024)** – Johnson & Johnson today announced data from the Phase 3 PERSEUS study showing deepening of responses and sustained minimal residual disease (MRD) negativity at both $10^{-5}$ and $10^{-6}$ levels with an induction regimen of DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) followed by a maintenance regimen of DARZALEX *FASPRO*® plus lenalidomide (D-R) for the treatment of patients with transplant-eligible (TE) newly diagnosed multiple myeloma (NDMM). The rates of deep and sustained MRD negativity were associated with improved progression-free survival (PFS) with DARZALEX *FASPRO*®-based quadruplet induction, consolidation and doublet maintenance regimen in these patients versus VRd. The data are featured as oral presentations at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #7502) and the 2024 European Hematology Association (EHA) Congress (Abstract #S201).

“MRD-negativity is an important measure in predicting long-term progression-free survival for patients with multiple myeloma,” said Dr. Paula Rodriguez-Otero, Department of Hematology, Cancer Center Clínica Universidad de Navarra, Pamplona, Navarra, Spain.* “The higher rates of deep and sustained MRD negativity with this DARZALEX *FASPRO*-based regimen underscore the potential of D-VRd and D-R maintenance to shift the treatment paradigm for transplant-eligible patients with newly diagnosed multiple myeloma and bring us closer to the potential for a functional cure.”

In the PERSEUS study, the D-VRd arm showed deeper responses and higher rates of MRD negativity over time at both $10^{-5}$ and $10^{-6}$ levels compared to the VRd arm (n=354), with higher rates of complete response at the end of consolidation (44.5 percent vs. 34.7 percent) and maintenance (87.9 percent vs. 70.1 percent). Rates of MRD negativity at $10^{-6}$ increased over time and were consistently higher in the D-VRd vs. VRd arm: 43.9 percent vs. 20.9 percent (*P*=0.0001) at 12 months; 57.7 percent vs. 27.4 percent (*P*=0.0001) at 24 months and 63.9 percent vs. 30.8 percent (*P*=0.0001) at 36 months.[1]

The D-VRd arm also demonstrated higher rates of sustained MRD negativity at $10^{-6}$ for at least 12 months compared to the VRd arm: 47.3 percent vs. 18.6 percent (P <0.0001). The PFS rate at 48 months was 84.3 percent for the D-VRd arm compared to 67.7 percent for the VRd arm (hazard ratio [HR], 0.42; 95 percent confidence interval [CI], 0.30-0.59; *P*<0.0001).[1]

## Final survival analysis from Phase 3 MAIA study of DARZALEX®-based regimen as a frontline combination therapy to be presented at EHA

Follow-up data from MAIA showed a median overall survival of 7.5 years for DARZALEX® plus lenalidomide and dexamethasone (D-Rd), with a 33 percent reduction in the risk of death versus lenalidomide plus dexamethasone (Rd) in transplant-ineligible patients with NDMM (HR, 0.67;95 percent CI,0.55-0.82; nominal *P*<0.0001).[2] Median overall survival was 90.3 months with D-Rd versus 64.1 months with Rd. The overall survival benefit with D-Rd versus Rd was consistent across

pre-specified subgroups.[2] The median age of patients enrolled in MAIA was 73 (range: 45 to 90) years, with 43.6 percent of participants over the age of 75 years.[2] Data will be presented in a poster at EHA (Abstract #P968).

“The median overall survival of 7.5 years seen in the MAIA study reinforces the efficacy of DARZALEX as a foundational treatment in the frontline setting for patients with multiple myeloma who are not eligible for transplant,” said Jordan Schecter, M.D., Vice President, Disease Area Leader, Multiple Myeloma, at Johnson & Johnson Innovative Medicine. “DARZALEX has shown an overall survival benefit across three studies in newly diagnosed multiple myeloma, supporting it as a standard-of-care. DARZALEX-based quadruplet and triplet regimens have advanced outcomes for newly diagnosed patients in the transplant-eligible and ineligible settings.”

## Long-term data from Phase 3 CASSIOPEIA study evaluating DARZALEX®-based therapy and maintenance in TE patients with NDMM to be presented at EHA

More than six years of follow-up data from CASSIOPEIA show that post-transplant maintenance with DARZALEX® reduced the risk of disease progression or death by 51 percent versus observation, with the median PFS not reached at six years with DARZALEX® vs median PFS of less than four years (45.8 months) with observation (HR, 0.49; 95 percent CI, 0.40 - 0.59; *P*< 0.0001).[3] The results will be presented in an oral presentation at EHA (Abstract #S204).

In the PERSEUS, MAIA and CASSIOPEIA studies, the safety profiles were consistent with the known safety profiles for DARZALEX® and DARZALEX *FASPRO*®.[1,2,3]

* Dr. Paula Rodriguez-Otero, Department of Hematology, Cancer Center Clínica Universidad de Navarra, has provided consulting, advisory, and speaking services to Johnson & Johnson; she has not been paid for any media work.

**About the PERSEUS study**
The PERSEUS study (NCT03710603) is being conducted in collaboration with the European Myeloma Network as the sponsor. PERSEUS is an ongoing, randomized, open-label, Phase 3 study comparing the efficacy and safety of D-VRd and ASCT followed by D-R maintenance vs VRd and ASCT followed by R maintenance in patients with transplant-eligible NDMM. The primary endpoint is PFS, and secondary endpoints include overall CR or better rate, overall MRD-negativity (in patients with CR or better), and overall survival. DARZALEX *FASPRO*® was discontinued after at least 24 months of D-R maintenance therapy in patients who had a CR or better and had sustained MRD–negative status for at least 12 months.[4] The median age is 61.0 (range, 32-70) years for patients in the D-VRd arm and 59.0 (range, 31-70) years for patients in the VRd arm. The study is being conducted in 14 countries in Europe and Australia.

Data from the PERSEUS study were featured as a late-breaking oral presentation (LBA-1) at the 2023 American Society of Hematology (ASH) Annual Meeting and simultaneously published in *The New England Journal of Medicine* in 2023.

**About the MAIA Trial**
The randomized, open-label, multicenter Phase 3 (NCT02076009) study included 737 newly diagnosed patients with multiple myeloma ineligible for high-dose chemotherapy and autologous stem cell transplant (ASCT), aged 45-90 years (median age of 73).[5] Patients were randomized to receive either D-Rd or Rd alone in 28-day cycles. In the D-Rd arm, patients received DARZALEX® 16 milligrams per kilogram (mg/kg) IV weekly for cycles 1 – 2, every two weeks for cycles 3 – 6 and every four weeks for cycle 7 and thereafter.[5] Patients in the D-Rd and Rd treatment arms received 25 mg of lenalidomide on days 1 – 21 of each 28-day cycle, and dexamethasone at 40 mg once a week for each cycle. Patients in both treatment arms continued until disease progression or unacceptable toxicity.[6]

Earlier results from the MAIA study supported the U.S. Food and Drug Administration (FDA) approval of DARZALEX® in combination with Rd. These data were also published in *The New England Journal of Medicine* in 2019. An updated OS analysis was published in *The Lancet Oncology* in 2021.

**About the CASSIOPEIA Trial**
The randomized, open-label, multicenter, Phase 3 (NCT02541383) study is sponsored by the French Intergroupe Francophone du Myelome in collaboration with the Dutch-Belgian Cooperative Trial Group for Hematology Oncology and Janssen Research & Development, LLC. This Phase 3 study included 1,085 newly diagnosed patients with previously untreated, symptomatic multiple myeloma who were eligible for high-dose chemotherapy and stem cell transplant. Part one of the study compared DARZALEX® (D) in combination with bortezomib, thalidomide and dexamethasone (VTd) versus VTd induction and consolidation therapy in patients with NDMM who were eligible for autologous stem cell transplantation (ASCT) and demonstrated that D-VTd yielded deeper responses and improved PFS. Part two of the study compared D-maintenance therapy given every 8 weeks (at a reduced frequency treatment schedule compared to the standard long-term dosing frequency of every 4 weeks) versus observation. The primary endpoint in this part of the study is the proportion of patients who achieve a sCR 100 days after transplant. In the second part of the study, which is ongoing, patients who achieved a partial response or better in part one will undergo a second randomization to receive maintenance treatment with DARZALEX® 16 mg/kg every eight weeks for up to two years or will be observed with no further treatment. The primary endpoint in this part of the study is PFS.[7]

**About Multiple Myeloma**
Multiple myeloma is a blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[8] In multiple myeloma, these malignant plasma cells proliferate and replace normal cells in the bone marrow.[9] Multiple myeloma is the second most common blood cancer worldwide and remains an incurable disease.[10] In 2024, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 will die from the disease.[11] People with multiple myeloma have a 5-year survival rate of 59.8 percent.[8] While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.[12,13]

**About DARZALEX *FASPRO*® and DARZALEX®**

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) received U.S. FDA approval in May 2020 and is approved for eight indications in multiple myeloma, three of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.[14] It is the only subcutaneous CD38-directed antibody approved to treat patients with MM. DARZALEX *FASPRO*® is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

DARZALEX® (daratumumab) received U.S. FDA approval in November 2015 and is approved in eight indications, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.[6]

DARZALEX® is the first CD38-directed antibody approved to treat multiple myeloma.[6] DARZALEX®-based regimens have been used in the treatment of more than 518,000 patients worldwide and more than 68,000 patients in the U.S. alone.

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize daratumumab.

Since 2020, the National Comprehensive Cancer Network® (NCCN®) has recommended daratumumab-based combination regimens for the treatment of newly diagnosed multiple myeloma and relapsed and refractory multiple myeloma.† For newly diagnosed multiple myeloma in non-transplant candidates, the NCCN® guidelines recommend daratumumab in combination with lenalidomide and dexamethasone as a Category 1 preferred regimen; daratumumab in combination with bortezomib, melphalan, and prednisone as another recommended Category 1 regimen; and daratumumab in combination with bortezomib, cyclophosphamide, and prednisone as another recommended Category 2A regimen. For newly diagnosed multiple myeloma in transplant candidates, the NCCN® guidelines recommend daratumumab in combination with bortezomib, lenalidomide and dexamethasone as another recommended Category 2A regimen; daratumumab in combination with bortezomib, thalidomide and dexamethasone as a Category 2A regimen useful in certain circumstances; daratumumab in combination with carfilzomib, lenalidomide and dexamethasone as a Category 2A regimen useful in certain circumstances; and daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone as a Category 2A regimen useful in certain circumstances. For maintenance in transplant candidates, the NCCN guidelines recommend daratumumab in combination with lenalidomide as useful in certain circumstances. In relapsed/refractory myeloma, four daratumumab regimens are listed as Category 1 preferred regimens for early relapses (1-3 prior therapies): daratumumab in combination with lenalidomide and dexamethasone; daratumumab in combination with bortezomib and dexamethasone; daratumumab in combination with carfilzomib and dexamethasone; and daratumumab in combination with pomalidomide and dexamethasone [after one prior therapy including lenalidomide and a proteasome inhibitor (PI)]. The NCCN® also recommends daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone as another Category 2A regimen for early relapses (1-3 prior therapies) and as monotherapy as a Category 2A regimen useful in certain circumstances for early relapse patients after at least three prior therapies, including a PI and an immunomodulatory agent, or for patients who are double refractory to a PI and an immunomodulatory agent.

For more information, visit www.DARZALEX.com.

**DARZALEX® INDICATIONS AND IMPORTANT SAFETY INFORMATION**

**INDICATIONS**

DARZALEX® (daratumumab) 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
- 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 proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

**CONTRAINDICATIONS**

DARZALEX® is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

**WARNINGS AND PRECAUTIONS**

**Infusion-Related Reactions**

DARZALEX® 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®. 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® dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX® 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® 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 infusion. If ocular symptoms occur, interrupt DARZALEX infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX.

**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 infusion. 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 is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX®. Type and screen patients prior to starting DARZALEX®.

**Neutropenia and Thrombocytopenia**

DARZALEX® 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® until recovery of neutrophils or for recovery of platelets.

**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.

**Embryo-Fetal Toxicity**

Based on the mechanism of action, DARZALEX® can cause fetal harm when administered to a pregnant woman. DARZALEX® 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® and for 3 months after the last dose.

The combination of DARZALEX® 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.

**ADVERSE REACTIONS**

The most frequently reported adverse reactions (incidence ≥20%) 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® are: neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

Please click here to see the full Prescribing Information.

**DARZALEX *FASPRO*® INDICATIONS AND IMPORTANT SAFETY INFORMATION**

**INDICATIONS**

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
- 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 proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

**CONTRAINDICATIONS**
DARZALEX *FASPRO*® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

**WARNINGS AND PRECAUTIONS**

**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*®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX *FASPRO*®.

*Systemic Reactions*
In a pooled safety population of 898 patients with multiple myeloma (N=705) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*® as monotherapy or in combination, 9% of patients experienced a systemic administration-related reaction (Grade 2: 3.2%, Grade 3: 1%). Systemic administration-related reactions occurred in 8% of patients with the first injection, 0.3% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 140 systemic administration-related reactions that occurred in 77 patients, 121 (86%) 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*®. Consider administering corticosteroids and other medications after the administration of DARZALEX *FASPRO*® 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*® and seek immediate ophthalmologic evaluation prior to restarting DARZALEX *FASPRO*®.

*Local Reactions*
In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.7%. 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*®. Monitor for local reactions and consider symptomatic management.

**Neutropenia**
Daratumumab may increase neutropenia 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 *FASPRO*® until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO*®, higher rates of Grade 3-4 neutropenia were observed.

**Thrombocytopenia**
Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX *FASPRO*® until recovery of platelets.

**Embryo-Fetal Toxicity**
Based on the mechanism of action, DARZALEX *FASPRO*® can cause fetal harm when administered to a pregnant woman. DARZALEX *FASPRO*® 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 *FASPRO*® and for 3 months after the last dose.
The combination of DARZALEX *FASPRO*® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide prescribing information on use during pregnancy.

**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 *FASPRO*®. Type and screen patients prior to starting 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 DARZALEX *FASPRO*®-treated patients with IgG kappa myeloma protein.

**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 sensory neuropathy, constipation, pneumonia, and peripheral edema.
The most common hematology laboratory abnormalities (≥40%) with DARZALEX *FASPRO*® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

**Please click here to see the full Prescribing Information.**

**About Johnson & Johnson**

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JanssenUS and @JNJInnovMed. Janssen Research & Development, LLC, and Janssen Biotech, Inc., are Johnson & Johnson companies.

***Cautions Concerning Forward-Looking Statements***

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) and DARZALEX® (daratumumab). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections Janssen Research & Development, LLC, Janssen Biotech, Inc., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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[1] Rodríguez-Otero P, et al. Daratumumab (DARA) + bortezomib/lenalidomide/dexamethasone (VRd) in transplant-eligible (TE) patients (pts) with newly diagnosed multiple myeloma (NDMM): Analysis of minimal residual disease (MRD) in the PERSEUS trial. 2024 American Society for Clinical Oncology Annual Meeting. June 3, 2024.

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