Johnson&Johnson

NEWS RELEASE

DARZALEX FASPRO®-based quadruplet regimen approved in the U.S. for newly diagnosed patients with multiple myeloma who are transplant ineligible

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Quadruplet regimen demonstrated significantly deeper and more durable responses, higher MRD negativity and improved progression-free survival versus a standard of care

Approval marks the twelfth indication for DARZALEX FASPRO® and fifth in the newly diagnosed setting, underscoring its role as foundational therapy for both newly diagnosed and relapsed/refractory multiple myeloma patients

HORSHAM, Pa., Jan. 27, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) announced today the U.S. Food and Drug Administration (FDA) approved DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are ineligible for autologous stem cell transplant (ASCT). D-VRd is the only anti-CD38 antibody-based regimen with approved indications across newly diagnosed patients, regardless of transplant eligibility.

The pivotal Phase 3 CEPHEUS study (**NCT03652064**) evaluated the efficacy and safety of D-VRd compared to bortezomib, lenalidomide and dexamethasone (VRd) in NDMM patients who were ineligible for ASCT or deferred ASCT as initial therapy.[1] Today's milestone follows approval for D-VRd for the treatment of patients who are newly diagnosed with multiple myeloma and eligible for ASCT.[2]

"D-VRd increased the depth and durability of responses, significantly reduced the risk of disease progression or death, and nearly doubled the rate of sustained minimal residual disease (MRD)-negativity compared to VRd in

patients ineligible for ASCT, solidifying this regimen as a potential standard of care for newly diagnosed patients with multiple myeloma," said Saad Z. Usmani, M.D., Chief, Myeloma Service, Memorial Sloan Kettering Cancer Center and CEPHEUS principal investigator.* "MRD-negativity is a potential predictor of prolonged progression-free and overall survival and D-VRd is now the only quadruplet regimen approved by the FDA based on a study with MRD-negativity as a primary endpoint."

"This approval marks the twelfth indication for DARZALEX FASPRO overall and fifth in newly diagnosed multiple myeloma, underscoring its role as foundational therapy for both newly diagnosed and relapsed/refractory patients," said June Lanoue, U.S. President, Hematology, Johnson & Johnson Innovative Medicine. "CEPHEUS demonstrated the efficacy of a DARZALEX FASPRO-based quadruplet as a frontline standard of care. With this approval, patients can receive D-VRd when they are first diagnosed with multiple myeloma, an important milestone as we work to one day deliver a functional cure."

Findings from CEPHEUS showed that at a median follow-up of 22 months, the overall MRD-negativity rate at a sensitivity of 10^{-5} (no cancer cells detected within 100,000 bone marrow cells) was 52.3 percent vs 34.8 percent with VRd ($P<0.0005$).[1] At a median follow-up of 39 months, the proportion of patients achieving sustained MRD-negativity of ≥12 months almost doubled at 42.6 percent vs 25.3 percent ($P<0.0003$) and D-VRd also significantly reduced the risk of progression or death by 40 percent (hazard ratio [HR], 0.60; 95 percent confidence interval [CI], 0.41-0.88; $P<0.0078$) vs VRd.[1] At a median follow-up of nearly 5 years (59 months), D-VRd significantly increased the depth of response with higher rates of complete response or better at 81.2 percent vs 61.6 percent with VRd.[1] Overall survival data were not yet mature.[1] The effectiveness of D-VRd has not been established in patients who refused ASCT as initial therapy.

The overall safety results of DARZALEX FASPRO®+VRd were consistent with the adverse reactions seen for DARZALEX FASPRO® and VRd.[1] In the CEPHEUS study, the most common adverse events (≥20%) in patients with newly diagnosed multiple myeloma who received D-VRd were upper respiratory tract infection, sensory neuropathy, musculoskeletal pain, diarrhea, fatigue, edema, rash, motor dysfunction, COVID-19, constipation, sleep disorder, cough, pneumonia, renal impairment, dizziness, nausea, urinary tract infection, pyrexia, abdominal pain, dyspnea, decreased appetite, and bruising.[1]

About the CEPHEUS Study

CEPHEUS (**NCT03652064**) is a multicenter, randomized, open-label, Phase 3 study comparing the efficacy and safety of D-VRd vs VRd in patients with newly diagnosed multiple myeloma who were ineligible for autologous stem cell transplant (ASCT) or refused ASCT as initial therapy. The primary endpoint was overall minimal residual disease (MRD)-negativity rate at 10^{-5} sensitivity threshold. Secondary endpoints include complete response or better rate, progression-free survival (PFS), sustained MRD-negativity rate, MRD-negative rate at 1-year, overall response

rate, time to and duration of response, PFS on next line of therapy, overall survival and safety. The trial enrolled 395 patients in 13 countries across North America, South America, and Europe.

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.[3] In multiple myeloma, these malignant plasma cells proliferate and replace normal cells in the bone marrow.[4] Multiple myeloma is the second most common blood cancer worldwide and remains an incurable disease.[5] In 2026, it is estimated that more than 36,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 will die from the disease.[6] People with multiple myeloma have a 5-year survival rate of 59.8 percent.[6] 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.[7,8]

About DARZALEX FASPRO® and DARZALEX®

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) **received** U.S. FDA approval in May 2020 and is approved for eleven indications in multiple myeloma, five of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.[1] It is the only subcutaneous CD38-directed antibody approved to treat patients with multiple myeloma. 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. DARZALEX® is the first CD38-directed antibody approved to treat multiple myeloma.

DARZALEX®-based regimens have been used in the treatment of more than 720,000 patients worldwide.

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.

For more information, visit **www.DARZALEX.com**.

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

DARZALEX FASPRO® as monotherapy is indicated for the treatment of adult patients with high-risk smoldering multiple myeloma.

IMPORTANT SAFETY INFORMATION

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 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% 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 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) 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 of 1446 patients with multiple myeloma (N=1253) or light chain amyloidosis (N=193), injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 1.1%. The most frequent (>1%) injection-site reactions were injection site erythema and injection site rash. In patients with high-risk smoldering multiple myeloma (N=193), injection-site reactions occurred in 28% of patients, including Grade 2 reactions in 3%. These local reactions occurred a median of 6 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. Monitor for local reactions and consider symptomatic management.

Infections

DARZALEX FASPRO® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX FASPRO® in a pooled safety population including patients with smoldering multiple myeloma and light chain (AL) amyloidosis (N=1639), serious infections, including opportunistic infections, occurred in 24% of patients, Grade 3 or 4 infections occurred in 22%, and fatal infections occurred in 2.5%. The most common type of serious infection reported was pneumonia (8.5%).

Monitor patients for signs and symptoms of infection prior to and during treatment with DARZALEX FASPRO® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

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, sleep disorder, headache, rash, renal impairment, motor dysfunction, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, decreased appetite, urinary tract infection, abdominal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, dizziness, bruising, and COVID-19.

The most common adverse reactions (≥20%) in patients with high-risk smoldering multiple myeloma who received DARZALEX FASPRO® monotherapy are upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

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 read full Prescribing Information for DARZALEX FASPRO®.

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 read full Prescribing Information for DARZALEX®.

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.innovativemedicine.jnj.com.** Follow us **at @JNJInnovMed.**

Janssen Research & Development, LLC and Janssen Biotech, Inc. are both 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). 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 of 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 most recent Annual Report on Form 10-K, 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. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

*Dr. Saad Z. Usmani has provided consulting and advisory services to Johnson & Johnson; he has not been paid for any media work.

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[1]DARZALEX FASPRO® U.S. Prescribing Information.
[2]Johnson & Johnson Innovative Medicine. DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)-based quadruplet regimen approved in the U.S. for patients with newly diagnosed multiple myeloma who are transplant-eligible **https://www.jnj.com/media-center/press-releases/darzalex-faspro-daratumumab-and-hyaluronidase-fihj-based-quadruplet-regimen-approved-in-the-u-s-for-patients-with-newly-diagnosed-multiple-myeloma-who-are-transplant-eligible** Accessed January 2026.
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[8]American Cancer Society. Multiple Myeloma Early Detection, Diagnosis, and Staging. Accessed January 2026. Available at: **https://www.cancer.org/cancer/types/multiple-myeloma/detection-diagnosis-staging/detection.html**

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