Johnson&Johnson

NEWS RELEASE

TECVAYLI® monotherapy demonstrates superior progression-free and overall survival versus standard of care as early as first relapse in patients with multiple myeloma predominantly refractory to anti-CD38 therapy and lenalidomide

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TECVAYLI® alone reduced risk of disease progression or death by 71% in a high unmet need population

MajesTEC-9 is the second positive Phase 3 study to support TECVAYLI® regimens as a potential new standard of care as early as first relapse

RARITAN, N.J., Jan. 14, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ), a worldwide leader in multiple myeloma therapies, today announced positive topline results from the investigational Phase 3 MajesTEC-9 study of TECVAYLI® (teclistamab-cqyv) monotherapy, showing a 71% reduction in the risk of disease progression or death and a 40% reduction in the risk of death in a patient population that was predominantly refractory to anti-CD38 therapy and lenalidomide. Data confirm superior progression-free survival (PFS) and overall survival (OS) with TECVAYLI® compared to standard of care as early as second line.[1]

Multiple myeloma is a blood cancer characterized by high rates of relapse. Despite recent advances in treatment, a significant unmet need remains for additional, well–tolerated therapies—particularly in earlier lines of therapy for patients refractory to anti–CD38 monoclonal antibodies and lenalidomide, commonly used medications in multiple myeloma.

The MajesTEC-9 study evaluated TECVAYLI® monotherapy in patients predominantly refractory to anti-CD38 and

lenalidomide therapies.[1] These results build on the unprecedented **MajesTEC-3 findings** published in The New England Journal of Medicine, which showed significant PFS and OS benefits with TECVAYLI® plus DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) in patients who were naïve or sensitive to an anti-CD38 therapy.[2] These two distinct Phase 3 studies address the continuum of unmet need.[1,2,3]

"The MajesTEC-9 results reinforce the potential of TECVAYLI to transform treatment earlier in the multiple myeloma journey, with an immunotherapy regimen widely available for all appropriate patients, including those commonly treated in the community setting," said Roberto Mina, M.D., Associate Professor, Winship Cancer Institute of Emory University, formerly Assistant Professor, University of Turin, Turin, Italy.* "The impressive results show a significant improvement in progression-free and overall survival as a monotherapy in patients with refractory multiple myeloma, and together with the MajesTEC-3 results, help establish TECVAYLI as an essential therapy for patients as early as first relapse."

The MajesTEC-9 study evaluates the efficacy and safety of TECVAYLI®, a bispecific T-cell engager antibody therapy, versus the standard of care of pomalidomide, bortezomib, and dexamethasone (PVd) or carfilzomib and dexamethasone (Kd) in patients with relapsed/refractory multiple myeloma who have received 1 to 3 prior lines of therapy.[1] All patients in MajesTEC-9 had to have received a prior anti-CD38 monoclonal antibody and lenalidomide.[1] Overall, the majority of patients enrolled were refractory to anti-CD38 monoclonal antibodies (85%) and lenalidomide (79%), and more than 90% were refractory to their last line of therapy.[1]

Those randomized to TECVAYLI® had a clinically meaningful and statistically significant 71% reduction in the risk of progression or death [hazard ratio (HR)=0.29 (95% confidence interval (CI): 0.23, 0.38)] and a 40% reduction in the risk of death [HR=0.60 (95% CI: 0.43, 0.83)].[1] The safety profile of TECVAYLI® monotherapy was clinically manageable using established protocols and consistent with its known profile, with no new safety concerns identified.[1] Topline data were confirmed following this first pre-specified interim analysis. Based on the strength of the data, the Independent Data Monitoring Committee (IDMC) recommended unblinding the study.

"TECVAYLI continues to break new ground as a first-in-class bispecific T-cell engager antibody and the MajesTEC-9 results are the latest example of Johnson & Johnson's commitment to provide critical treatment options for patients at every stage of their disease," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Head, Oncology, Johnson & Johnson Innovative Medicine. "In addition to the other transformational therapies in our multiple myeloma portfolio, we continue to redefine the future for patients, bringing us another step closer to cure."

The full results of the Phase 3 MajesTEC-9 study will be presented at a future major medical meeting and shared with global health authorities.

About TECVAYLI®

TECVAYLI® (teclistamab-cqyv) is a first-in-class, bispecific T-cell engager antibody therapy that uses innovative science to activate the immune system by binding to the CD3 receptor expressed on the surface of T-cells and to the B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. TECVAYLI® received accelerated **approval** from the U.S. Food and Drug Administration (FDA) in October 2022 as an off-the-shelf (or ready-to-use) antibody that is administered as a subcutaneous treatment for adult patients with relapsed or refractory multiple myeloma (RRMM) who received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody.[4]

In February 2024, the U.S. FDA **approved** the supplemental Biologics License Application (sBLA) for TECVAYLI® for a reduced dosing frequency of 1.5 mg/kg every two weeks in patients with RRMM who achieved and maintained a complete response (CR) or better for a minimum of six months. Since FDA approval, more than 20,800 patients have been treated worldwide with TECVAYLI®.

The European Commission (EC) granted TECVAYLI® **conditional marketing authorization** in August 2022 as monotherapy for the treatment of adult patients with RRMM who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody, and have demonstrated disease progression since the last therapy. In August 2023, the EC **approved** a Type II variation application for TECVAYLI®, providing the option for a reduced dosing frequency of 1.5 mg/kg every two weeks (Q2W) in patients who have achieved a complete response or better for a minimum of six months.

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

About DARZALEX FASPRO® and DARZALEX®

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) **received** U.S. FDA approval in May 2020 and is approved for 11 indications in multiple myeloma, four of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.[5] 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.[6] In 2025, DARZALEX FASPRO® was approved by the U.S. FDA and EMA as the first and only treatment for patients with high-risk smoldering multiple myeloma.

DARZALEX® is the first CD38-directed antibody approved to treat multiple myeloma.[5] DARZALEX®-based regimens have been used in the treatment of more than 618,000 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.

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

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[5] In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors.[6] Multiple myeloma is the third most common blood cancer worldwide and remains an incurable disease.[7] In 2024, it was estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 people would die from the disease.[8] People living with multiple myeloma have a 5-year survival rate of 59.8 percent.[9] 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 and kidney problems or infections.[10,11]

TECVAYLI® IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in 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 TECVAYLI®. Initiate treatment with TECVAYLI® step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome - TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

TECVAYLI® is available only through a restricted program under a REMS.

Neurologic Toxicity including ICANS - TECVAYLI® can cause serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

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

TECVAYLI® is available only through a restricted program under a REMS.

TECVAYLI® and TALVEY® REMS - TECVAYLI® 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.

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI® at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%.

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

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Neutropenia - TECVAYLI® can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI® at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold TECVAYLI® based on severity.

Hypersensitivity and Other Administration Reactions - TECVAYLI® can cause both systemic administration-related and local injection-site reactions. Systemic Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, 1.2% of patients experienced systemic-administration reactions, which included Grade 1 recurrent pyrexia and Grade 1 swollen tongue. Local Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, injection-site reactions occurred in 35% of patients, with Grade 1 injection-site reactions in 30% and Grade 2 in 4.8%. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Embryo-Fetal Toxicity - Based on its mechanism of action, TECVAYLI® 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 TECVAYLI® and for 5 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥20%) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Please read full **Prescribing Information**, including Boxed WARNING, for TECVAYLI®.

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, 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 in combination, 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 reaction 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, insomnia, headache, rash, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, upper respiratory tract infection, , peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, peripheral edema, and anemia.

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 the 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 the 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.

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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 TECVAYLI® (teclistamab-cqyv) and 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.

Footnotes

*Roberto Mina, M.D., Associate Professor, Winship Cancer Institute of Emory University, formerly Assistant Professor, University of Turin, Turin, Italy, has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

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