

NEWS RELEASE

New model-based analysis further supports the potential of TECVAYLI® (teclistamab-cqyv) plus DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) to redefine long-term survival expectations in early line relapsed/refractory multiple myeloma

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- Analysis shows ~87% of patients treated with TECVAYLI® plus DARZALEX FASPRO® as early as second line were estimated to have comparable mortality risk to the general population
- A separate analysis shows the survival benefit was driven by a 90% reduction in the risk of multiple myeloma progression versus standard of care, with no significant difference in rates of non-relapse mortality
- Johnson & Johnson is advancing a differentiated multiple myeloma portfolio designed to deliver deeper, more durable disease control and improve long-term outcomes for patients

RARITAN, N.J., Sept. 23, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ), a worldwide leader in multiple myeloma therapies, today announced new data from the Phase 3 MajesTEC-3 study showing sustained disease control and survival with TECVAYLI® (teclistamab-cqyv) plus DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) in patients with relapsed or refractory multiple myeloma (RRMM) who had received 1-3 prior lines of therapy.^{1,2}

Using a relative survival mixture cure model (MCM) and actual progression-free survival (PFS) and overall survival (OS) data from the trial, statistical modeling estimated that ~87% of patients treated with TECVAYLI® plus DARZALEX FASPRO® (Tec-Dara) may experience a mortality risk and projected life expectancy similar to an age-matched

general population.¹ Modeling further predicted that median overall survival with Tec-Dara would be nearly four-fold longer than with the standard of care (SOC) comparator in the study, dexamethasone with pomalidomide or bortezomib (DPd/DVd). These data help to illustrate to what extent treatment with TECVAYLI® plus DARZALEX FASPRO® as early as second line may reshape survival expectations in multiple myeloma.¹

In the MajesTEC-3 study, TECVAYLI® plus DARZALEX FASPRO® significantly improved overall survival versus standard of care (SOC), with an estimated 83% of patients alive at 3 years.³ A post hoc analysis showed that Tec-Dara reduced the risk of cumulative incidence of disease progression by 90% versus SOC, with no significant difference in non-relapse mortality over time between the treatment arms.² These data (Abstract #OA-58 and Abstract #OA-49) will be presented in two oral sessions at the International Myeloma Society (IMS) Annual Meeting.

Expert and company perspectives emphasize the potential for durable, long-term disease control

"These findings underscore how consequential treatment choice at first relapse can be in shaping a patient's long-term trajectory," said Dr. Luciano J. Costa, Professor of Multiple Myeloma and Director of the Multiple Myeloma Research and Treatment Program at the University of Alabama at Birmingham.* "The sustained disease control observed with TECVAYLI plus DARZALEX FASPRO is changing expectations for what treatment can achieve in relapsed or refractory multiple myeloma, moving beyond just delaying the next relapse toward the possibility of durable long-term disease control."

"The continued analyses of the unprecedented MajesTEC-3 trial challenge long-held expectations of what may be possible in multiple myeloma," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. "Our ambition is to build on this progress by fundamentally changing the long-term trajectory of multiple myeloma and, ultimately, creating a future in which this disease is no longer defined as incurable."

Model-based analysis projects potential long-term survival outcomes

The MajesTEC-3 study evaluated TECVAYLI® plus DARZALEX FASPRO® versus investigator's choice of daratumumab SC plus DPd/DVd in patients with RRMM who had received one to three prior lines of therapy.³ In this analysis, a relative survival mixture cure model was applied to patients treated with TECVAYLI® plus DARZALEX FASPRO® (n=291) and DPd/DVd (n=296) to assess whether long-term disease control could translate into outcomes approaching those of the general population.¹ Best-fit models estimated cure fractions of 86.6% (95% confidence interval [CI], 81–91) for OS with the combination, compared with 0% (95% CI, 0–53) with DPd/DVd, with substantially greater uncertainty in the DPd/DVd estimates.¹ Model projected remaining life expectancy was 18.5 years with the combination, nearly four times the 4.9 years projected with DPd/DVd and approaching 21.1 years for the matched

general population.¹

Reduced disease progression drives survival benefit

A separate post hoc analysis provided further insight into the survival benefit observed in MajesTEC-3.² At 36 months, the cumulative incidence of disease progression was 8.7% with TECVAYLI[®] plus DARZALEX FASPRO[®], versus 62.1% with DPd/DVd, representing a 90% reduction in the risk of disease progression (subdistribution hazard ratio [sHR]=0.10; 95% CI, 0.07–0.16; P<0.0001).² The 36-month OS rate was 83.3% versus 65.0%, respectively (hazard ratio [HR]=0.46; 95% CI, 0.32–0.65; P<0.0001).² There was no significant difference in non-relapse mortality between treatment groups, with 36-month rates of 10.2% with TECVAYLI[®] plus DARZALEX FASPRO[®] and 9.0% with DPd/DVd (sHR=1.16; 95% CI, 0.69–1.98; P=0.5668).²

There was no difference in OS through 10 months (HR=1.08; 95% CI, 0.64–1.81).² Beyond 10 months, OS favored TECVAYLI[®] plus DARZALEX FASPRO[®], with a 78% reduction in the risk of death versus DPd/DVd (HR=0.22; 95% CI, 0.13–0.38).² A prespecified restricted mean survival time analysis also confirmed a significant OS benefit, with a difference of 2.15 months (P=0.0088).²

Together, these analyses provide complementary evidence supporting the long-term benefit observed with TECVAYLI[®] plus DARZALEX FASPRO[®]. While the MCM analysis suggests the potential for highly durable disease control to extend overall survival for patients with multiple myeloma relative to the general population, the competing risk analysis helps explain these outcomes by demonstrating a profound reduction in disease progression without a significant increase in non-relapse mortality. MajesTEC-3 is ongoing, and continued follow-up will assess whether observed outcomes confirm these model-based predictions.

About the MajesTEC-3 study

MajesTEC-3 (**NCT05083169**) is an ongoing, Phase 3 randomized study evaluating the safety and efficacy of teclistamab plus daratumumab SC versus investigator's choice of daratumumab SC and dexamethasone with either pomalidomide or bortezomib (DPd/DVd) in patients with relapsed/refractory multiple myeloma who have received 1–3 prior lines of therapy. The primary endpoint is progression-free survival (PFS) and secondary endpoints include complete response or better (≥CR), overall response rate (ORR), minimal residual disease (MRD)-negativity (10⁻⁵ by next-generation sequencing), overall survival (OS), time to worsening of symptoms (MySIm-Q), and safety. The MajesTEC-3 study is a part of the MajesTEC clinical program, which includes exploring the potential of teclistamab as a combination regimen.

About multiple myeloma

Multiple myeloma is a complex blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.⁴ In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors.⁵ Multiple myeloma is the second most common blood cancer worldwide.⁶ More than 180,000 new cases of multiple myeloma are diagnosed globally each year.⁷ People living with multiple myeloma have a 5-year survival rate of 59.8%.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 and kidney problems or infections.^{9,10} In recent years, overall survival has improved from years to decades, with effective treatment options now available across every stage and line of therapy.¹¹

About Johnson & Johnson's multiple myeloma portfolio

Johnson & Johnson is a global leader in multiple myeloma therapies, with a broad and differentiated portfolio designed to address the complexity and heterogeneity of the disease. Our portfolio spans multiple mechanisms of action, targets and treatment modalities, including CD38-directed therapies, BCMA- and GPRC5D-targeting bispecific antibodies, and cellular therapies.

Over the past decade, Johnson & Johnson therapies have helped extend survival for patients with multiple myeloma from just a few years to a decade or more. With the right medicines, used as early as possible, combined and sequenced for the best results, Johnson & Johnson is expanding treatment options to match the right therapy to the right patient at the right stage of disease and drive deeper and more durable responses.

In August 2026, the EC **approved** an indication extension for TECVAYLI® in combination with daratumumab for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received at least one prior therapy. The approval introduces a new treatment option as early as second line for patients living with RRMM.

Through ongoing research and a robust clinical program, Johnson & Johnson is committed to transforming multiple myeloma into a more manageable condition that is no longer treated to progression but has the potential to, ultimately, be cured.

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.¹²

In March 2026, the U.S. FDA **approved** TECVAYLI® in combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent. The supplemental Biologics License Application was proactively selected for the Commissioner's National Priority Voucher Pilot Program and also granted the application Breakthrough Therapy Designation and Real-Time Oncology Review. This approval expanded the use of TECVAYLI® into earlier lines of therapy and is the first bispecific antibody-based combination regimen in this setting.

To date, more than 30,000 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.

In August 2026, the EC **approved** an indication extension for TECVAYLI® in combination with daratumumab for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received at least one prior therapy. The approval introduces a new treatment option as early as second line for patients living with RRMM.

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, five of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.¹³ 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.¹⁴ 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. DARZALEX®-based regimens have been used in the treatment of more than 830,000 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**.

TECVAYLI® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS 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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
- as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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, life-threatening, or fatal 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 trials (monotherapy and combination therapy; N=448), CRS occurred in 64% of patients who received TECVAYLI at the recommended dosage, with Grade 1 CRS occurring in 46% of patients, Grade 2 in 18%, and Grade 3 in 0.2%. Recurrent CRS occurred in 27% of patients. Most patients experienced CRS during the initial step-up dosing schedule (step-up dose 1 [37%], step-up dose 2 [32%], or the initial treatment dose [20%]). CRS first occurred following subsequent doses of TECVAYLI in 2.5% of patients. The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose and the median duration of CRS was 2 (range: 1 to 22) 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 the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold until CRS resolves or permanently discontinue TECVAYLI based on severity.

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

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome

- TECVAYLI can cause serious, life-threatening, or fatal neurologic toxicity, including immune effector cell associated neurotoxicity syndrome (ICANS).

In the clinical trials (monotherapy and combination therapy trials; N=448), neurologic toxicity occurred in 60% of patients who received TECVAYLI at the recommended dosage, with Grade 3 or 4 neurologic toxicity in 6%. Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor

dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%). Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (one patient each).

In MajesTEC-1, ICANS was reported in 6% of patients who received TECVAYLI as monotherapy at the recommended dosage. 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 TECVAYLI doses. 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.

In MajesTEC-3, ICANS was reported in 1.1% of patients who received the recommended TECVAYLI dosage in combination with daratumumab and hyaluronidase-fihj, including Grade 4 ICANS in 1 patient. All events of ICANS occurred during the step-up dosing schedule. The median time to onset of ICANS was 2 (range: 1 to 3) days after the most recent dose and the median duration of ICANS was 2 (range: 1 to 2) days. The clinical manifestations of ICANS reported were amnesia, encephalopathy and delirium.

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, including ICANS during TECVAYLI treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold until neurologic toxicity resolves 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 receiving TECVAYLI 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. There was one fatal case of hepatic failure in MajesTEC-1. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448) elevated aspartate aminotransferase (AST) occurred in 47% of patients, with Grade 3 or 4 elevations in 2.9%. Elevated alanine aminotransferase (ALT) occurred in 48% of

patients, with Grade 3 or 4 elevations in 3.8%. Elevated total bilirubin occurred in 10% of patients with Grade 3 or 4 elevations in 0.7%. 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 MajesTEC-1 (N=165), in patients who received the recommended TECVAYLI dosage, serious infections, including opportunistic infections, occurred in 30% of patients, Grade 3 or 4 infections in 35% of patients, and fatal infections in 4.2% of patients.

In MajesTEC-3 (N=283), in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj at the recommended dosage, serious infections, including opportunistic infections, occurred in 54% of patients, Grade 3 or Grade 4 infections in 54% of patients, and fatal infections in 4.6% of patients.

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.

Withhold TECVAYLI or consider permanent discontinuation of TECVAYLI based on severity.

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

Neutropenia - TECVAYLI can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), decreased neutrophils occurred in 88% of patients, with Grade 3 or 4 decreased neutrophils in 70%. Febrile neutropenia occurred in 6% 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 the recommended TECVAYLI dosage in the clinical trials

(monotherapy and combination therapy trials; N=448), 2.5% of patients experienced systemic administration reactions, which included recurrent pyrexia and rash.

Local Reactions - In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), injection-site reactions occurred in 37% of patients, with Grade 1 injection-site reactions in 29% and Grade 2 in 9%.

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 patient. Advise pregnant patients 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 ($\geq 20\%$) in patients who received TECVAYLI monotherapy were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common adverse reactions ($\geq 20\%$) in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj were hypogammaglobulinemia, upper respiratory tract infection, CRS, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

The most common Grade 3 to 4 laboratory abnormalities ($\geq 20\%$) with TECVAYLI (as monotherapy or in combination with daratumumab and hyaluronidase-fihj) 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® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

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

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

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

- In combination with bortezomib, 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

IMPORTANT SAFETY INFORMATION

DARZALEX[®] AND DARZALEX FASPRO[®]: CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

DARZALEX[®]: 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 autologous stem cell transplant (ASCT) (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX[®], 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[®].

DARZALEX FASPRO[®]: 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 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.

DARZALEX® and DARZALEX FASPRO®: Infections

DARZALEX® and DARZALEX FASPRO® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX® in a pooled safety population (N=2066), serious infections, including opportunistic infections, occurred in 22.6% of patients, Grade 3 or 4 infections occurred in 24.3%, and fatal infections occurred in 1.2%. The most common (≥2%) types of serious infection reported were pneumonia (11%), upper respiratory tract infection (4%), sepsis (3%), and bronchitis (2%). 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® or DARZALEX FASPRO® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

DARZALEX® and DARZALEX FASPRO®: Neutropenia and Thrombocytopenia

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

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

DARZALEX® and DARZALEX FASPRO®: Interference With Serological Testing

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

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

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

DARZALEX® and DARZALEX FASPRO®: Embryo-Fetal Toxicity

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

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

DARZALEX®: ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence $\geq 20\%$) with DARZALEX® 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 ($\geq 40\%$) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

DARZALEX FASPRO®: ADVERSE REACTIONS

In multiple myeloma, the most common adverse reaction ($\geq 20\%$) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy ($\geq 20\%$ 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 hematologic laboratory abnormalities ($\geq 40\%$) 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®.

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

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.

Caution Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to 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, www.investor.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.

Footnote

¹ Dr. Luciano J. Costa, Professor of Multiple Myeloma and Director of the Multiple Myeloma Research and Treatment Program at the University of Alabama at Birmingham, has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

¹ Effelterre T, et al. Projecting Functional Cure in Patients (Pts) With Relapsed/Refractory Multiple Myeloma (RRMM) in the MajesTEC-3 Study of Teclistamab-Daratumumab (Tec-Dara) Using a Mixture Cure Model. Presented at: The 2026 International Myeloma Society (IMS) Annual Meeting; September 23, 2026; Glasgow, Sweden.

² Costa L, et al. Overall Survival, Progression and Non-Relapse Mortality With Teclistamab Plus Daratumumab (Tec-Dara) vs Dara-Based Triplets in Relapsed/Refractory Multiple Myeloma (RRMM): MajesTEC-3 Post Hoc Analysis. Presented at: The 2026 International Myeloma Society (IMS) Annual Meeting; September 24, 2026; Glasgow, Sweden.

³ MajesTEC-3, NCT05083169. A Phase 3 Randomized Study Comparing Teclistamab + Subcutaneous Daratumumab (Tec-Dara) Versus Daratumumab SC + Pomalidomide + Dexamethasone (DPd) or Daratumumab SC + Bortezomib + Dexamethasone (DVs).

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⁵ National Cancer Institute. Plasma cell neoplasms. Accessed September 2026. <https://www.cancer.gov/types/myeloma/patient/myeloma-treatment-pdq>

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⁷ International Agency for Research on Cancer (World Health Organization). Multiple myeloma fact sheet. 2024. Accessed September 2026. <https://gco.iarc.who.int/media/globocan/factsheets/cancers/35-multiple-myeloma-fact-sheet.pdf>

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¹¹ Kazandjian D. Multiple myeloma epidemiology and survival: a unique malignancy. J Clin Oncol. 2018;36(15):1479-1487. <https://pmc.ncbi.nlm.nih.gov/articles/PMC6119139/>

¹² Johnson & Johnson. U.S. FDA approves TECVAYLI® (teclistamab-cqyv), the first bispecific T-cell engager antibody for the treatment of patients with relapsed or refractory multiple myeloma. Accessed September 2026. <https://www.jnj.com/u-s-fda-approves-tecvayli-teclistamab-cqyv-the-first-bispecific-t-cell-engager-antibody-for-the-treatment-of-patients-with-relapsed-or-refractory-multiple-myeloma>

¹³ DARZALEX FASPRO® U.S. Prescribing Information. 2025. Horsham, PA: Janssen Biotech, Inc.

¹⁴ DARZALEX® U.S. Prescribing Information. 2022. Horsham, PA: Janssen Biotech, Inc.

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