Johnson&Johnson

NEWS RELEASE

# TECVAYLI® plus DARZALEX FASPRO® combination regimen significantly improves progression-free survival and overall survival versus standard of care

2025-10-16

First Phase 3 study (MajesTEC-3) of an investigational combination to show benefit in PFS and OS in relapsed/refractory multiple myeloma as early as second line

Independent Data Monitoring Committee (IDMC) recommended unblinding the study based on statistically significant results

RARITAN, N.J., Oct. 16, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ), the worldwide leader in multiple myeloma therapies, today announced positive topline results from the investigational Phase 3 MajesTEC-3 study. The study evaluates the efficacy and safety of TECVAYLI® (teclistamab-cqyv) in combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) versus investigator's choice of DARZALEX FASPRO, pomalidomide, and dexamethasone (DPd) or DARZALEX FASPRO, bortezomib, and dexamethasone (DVd) in patients with relapsed/refractory multiple myeloma (RRMM) who received one to three prior lines of therapy.[1]

At almost three years follow-up, the combination of TECVAYLI and DARZALEX FASPRO met the primary endpoint of progression-free survival (PFS) (the time a treatment keeps a patient's cancer from progressing or death) and the results were statistically significant and superior to standard of care.[2] The secondary endpoint of overall survival (OS) was also statistically significant at this first interim analysis.[2]

"TECVAYLI is the most utilized BCMA bispecific in later lines of myeloma treatment, supported by extensive clinical and real-world evidence. These results demonstrate the clinical benefits of TECVAYLI in earlier lines when used in combination, as evidenced by meaningful progression-free survival and overall survival outcomes," said Maria-

Victoria Mateos, M.D., Ph.D., Consultant Physician in Hematology, University Hospital of Salamanca.* "TECVAYLI and DARZALEX FASPRO uniquely work together to target both BCMA and CD38 simultaneously, priming and activating the immune system and eliminating myeloma cells."

MajesTEC-3 is the first Phase 3 study to show that the combination of TECVAYLI and DARZALEX FASPRO offers better PFS and OS than current standards of care.[2] Based on these statistically significant results at the interim analysis, the IDMC recommended unblinding the study.[2]

"The MajesTEC-3 study results of TECVAYLI plus DARZALEX FASPRO, two of our most important agents, demonstrate Johnson & Johnson's leadership in developing regimens with complementary and synergistic mechanisms of action for patients with multiple myeloma. We are confident this combination is poised to be a new standard of care option," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. "The increase in progression-free survival and overall survival is another example of how our portfolio is fundamentally transforming how patients with multiple myeloma are treated."

The overall safety profile of TECVAYLI administered in combination with DARZALEX FASPRO was consistent with the known safety profiles of each monotherapy.

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

## Additional data on the TECVAYLI and DARZALEX FASPRO combination

Recently **presented** results from the Phase 2 MajesTEC-5 study of the same investigational combination of TECVAYLI and DARZALEX FASPRO showed meaningful clinical efficacy. In transplant-eligible patients with newly diagnosed multiple myeloma, a 100 percent overall response rate was achieved when given as the first treatment after diagnosis.[3] Additionally, all minimal residual disease (MRD)-evaluable patients were MRD negative at the end of the induction period and successful stem cell mobilization was completed in 96% of patients.[3]

## 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 was **approved** by the U.S. 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 have 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 relapsed or refractory multiple myeloma who have achieved and maintained a CR or better for a minimum of six months. Since FDA approval, more than 18,400 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 **granted the approval** of 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 ®

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

U.S. FDA **approved** DARZALEX in November 2015 and it is now approved in ten indications. DARZALEX is the first CD38-directed antibody approved to treat multiple myeloma, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.[18] DARZALEX-based regimens have been used in the treatment of more than 618,000 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.

Since 2020, the National Comprehensive Cancer Network® (NCCN®) has recommended daratumumab-based combination regimens for the treatment of newly diagnosed multiple myeloma and relapsed and refractory multiple myeloma.[†] For newly diagnosed multiple myeloma in non-transplant candidates, the NCCN® guidelines recommend daratumumab in combination with lenalidomide and dexamethasone as a Category 1 preferred regimen; daratumumab in combination with bortezomib, melphalan, and prednisone as another recommended Category 1 regimen; and daratumumab in combination with bortezomib, cyclophosphamide, and prednisone as another recommended Category 2A regimen. For newly diagnosed multiple myeloma in transplant candidates, the NCCN® guidelines recommend daratumumab in combination with bortezomib, lenalidomide and dexamethasone as another recommended Category 2A regimen; daratumumab in combination with bortezomib, thalidomide and

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

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

## 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

## 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).

## 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).

## 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® INDICATIONS AND IMPORTANT SAFETY INFORMATION

## INDICATIONS

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

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

## CONTRAINDICATIONS

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

## WARNINGS AND PRECAUTIONS

### Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension and blurred vision.

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

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

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

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to

ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with DARZALEX infusion. If ocular symptoms occur, interrupt DARZALEX infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX.

## Interference With Serological Testing

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

## Neutropenia and Thrombocytopenia

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

## Interference With Determination of Complete Response

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

## Embryo-Fetal Toxicity

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

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

## ADVERSE REACTIONS

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

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

## 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, Janssen Biotech, Inc., Janssen Global Services, LLC and Janssen Scientific Affairs, LLC are Johnson & Johnson companies.

## Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of 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

*Maria-Victoria Mateos, M.D., Ph.D., Consultant Physician in Hematology, University Hospital of Salamanca, has provided consulting, advisory, and speaking services to Johnson & Johnson; she has not been paid for any media work.

[1] TECVAYLI® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.

[2]Janssen Research & Development, LLC. A Phase 3 Randomized Study Comparing Teclistamab in Combination With Daratumumab SC (Tec-Dara) Versus Standard Regimens in Relapsed or Refractory Multiple Myeloma (MajesTEC-3). **ClinicalTrials.gov**. Updated July 20, 2025. Available at: **https://clinicaltrials.gov/study/NCT05083169**

[3] Raab, Marc, S., et al, Post-Induction Outcomes and Updated Minimal Residual Disease Analysis From GMMG-HD10/DSMM-XX (MajesTEC-5): a Study of Teclistamab-Based Induction Regimens in Newly Diagnosed Multiple Myeloma (NDMM). 2025 International Myeloma Society Annual Meeting. September 2025.

[4] U.S. Food and Drug Administration. FDA Approves TECVAYLI® (teclistamab-cqyv), the First Bispecific T-cell Engager Antibody for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma. October 25, 2022. Available at: **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**

[5] Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. Am J Hematol. 2020;95(5):548-5672020;95(5):548-567. **http://www.ncbi.nlm.nih.gov/pubmed/32212178**

[6] National Cancer Institute. Plasma Cell Neoplasms. **https://www.cancer.gov/types/myeloma/patient/myeloma-treatment-pdq**. Accessed October 2025.

[7] City of Hope. Multiple Myeloma: Causes, Symptoms & Treatments. **https://www.cancercenter.com/cancer-types/multiple-myeloma**. Accessed October 2025.

[8] American Cancer Society. Key Statistics About Multiple Myeloma. **https://cancerstatisticscenter.cancer.org/types/myeloma**. Accessed October 2025.

[9]SEER Explorer: An interactive website for SEER cancer statistics [Internet]. Surveillance Research Program, National Cancer Institute. **https://seer.cancer.gov/explorer/**. Accessed October 2025.

[10] American Cancer Society. What is Multiple Myeloma? **https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html**. Accessed October 2025.

[11] American Cancer Society. Multiple Myeloma Early Detection, Diagnosis, and Staging. **https://www.cancer.org/cancer/types/multiple-myeloma/detection-diagnosis-staging/detection.html**. Accessed

October 2025.

View original content to download multimedia:**https://www.prnewswire.com/news-releases/tecvayli-plus-darzalex-faspro-combination-regimen-significantly-improves-progression-free-survival-and-overall-survival-versus-standard-of-care-302585407.html**

SOURCE Johnson & Johnson