

Data Featured at ASH 2026

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December 12-15, 2026

**Details on online publication abstracts to be released in early December*

Johnson & Johnson-sponsored teclistamab studies

Abstract number	Title	Presentation time (CST)
Multiple myeloma		
Oral Presentation		
Abstract #0695	Rapid and sustained debulking of myeloma disease burden with teclistamab in combination with daratumumab is associated with expanded cytotoxic adaptive immunity: A pharmacodynamic analysis of **MajesTEC-3**	Dec. 13, 2026 5:30 – 5:45 PM
Poster Presentations		
Abstract #2275	Does continuous immunoglobulin replacement (IgRT) reduce the risk of high-grade infections with bispecific antibody (BsAb) therapy in relapsed/refractory multiple myeloma (RRMM): A marginal structural model (MSM) analysis of **MajesTEC-3** and **MajesTEC-9**	Dec. 12, 2026 5:30 – 7:30 PM
Abstract #2786	Real-world patient characteristics, treatment patterns, and survival in 4L and 5L multiple myeloma patients from the **HONEUR** European Network	Dec. 12, 2026 5:30 – 7:30 PM
Abstract #5776	Teclistamab in elderly patients with relapsed/refractory multiple myeloma: a post hoc analysis of the **REALiTEC-2** study	Dec. 14, 2026 6:00 – 8:00 PM
Abstract #6316	Updated results from **CoMMitmenTT-TEC**: A real-world (RW) study of teclistamab monotherapy in late-line relapsed/refractory multiple myeloma (RRMM) across North America, Europe, Latin America, and Asia	Dec. 14, 2026 6:00 – 8:00 PM

Johnson & Johnson-sponsored talquetamab studies

Abstract number	Title	Presentation time (CST)
Multiple myeloma		
Oral Presentations		
Abstract #0418	Timing and resolution of oral side effects of talquetamab (Tal) with or without prophylactic interventions in patients (pts) with relapsed/refractory multiple myeloma (RRMM) in **TALisman**	Dec. 12, 2026 4:45 – 5:00 PM
Abstract #0426	Primary Analysis of the phase 3 randomized **MonumenTAL-6** study of teclistamab (Tec) plus talquetamab (Tal) or Tal plus pomalidomide (Pom) vs investigator's choice of elotuzumab, Pom and dexamethasone (EPd) or Pom, bortezomib, and dexamethasone (PVd) in patients (pts) with relapsed/refractory multiple myeloma (RRMM) and 1–4 prior lines of therapy (LOT)	Dec. 12, 2026 5:15 – 5:30 PM
Poster Presentations		
Abstract #2294	Pharmacodynamic mechanisms and biomarkers underlying clinical response to dual-antigen targeting combination of teclistamab (Tec) plus talquetamab (Tal) in patients with extramedullary (EMD) relapsed/refractory multiple myeloma (RRMM): translational analyses from **RedirecTT-1**	Dec. 12, 2026 5:30 – 7:30 PM
Abstract #4561	First results from **CoMMitmenTT-TAL**: A real-world (RW) study of talquetamab monotherapy in late-line relapsed/refractory multiple myeloma (RRMM) across North America, Europe, Latin America, and Asia	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #5770	Infections and humoral immunity in the phase 3 **MonumenTAL-3** study of talquetamab (Tal) plus daratumamab (Dara) with or without pomalidomide (Pom) in patients (pts) with relapsed/refractory multiple myeloma (RRMM)	Dec. 14, 2026 6:00 – 8:00 PM
Abstract #6310	Real-world outcomes of patients treated with talquetamab for relapsed or refractory multiple myeloma: A retrospective observational study in US academic centers	Dec. 14, 2026 6:00 – 8:00 PM

Johnson & Johnson-sponsored ramantamig studies

Abstract number	Title	Presentation time (CST)
Multiple myeloma		
	Oral Presentation	
Abstract #0110	Ramantamig, daratumumab (Dara), and lenalidomide (R) in patients with transplant-eligible (TE) newly diagnosed multiple myeloma (NDMM) in the phase 2 **MajesTEC-5** trial: First results of a trispecific antibody in NDMM	Dec. 12, 2026 9:45 – 10:00 AM

Johnson & Johnson-sponsored daratumumab studies

Abstract number	Title	Presentation time (CST)
Multiple myeloma		
Oral Presentations		
Abstract #0111	Minimal residual disease (MRD) negativity and MRD-guided daratumumab maintenance discontinuation with daratumumab, bortezomib, lenalidomide, and dexamethasone versus bortezomib, lenalidomide, and dexamethasone in transplant-eligible newly diagnosed multiple myeloma (TE-NDMM): Long-term analysis of the phase 3 **PERSEUS** study	Dec. 12, 2026 10:00 – 10:15 AM
Abstract #0112	Daratumumab monotherapy improves overall survival in patients with high-risk smoldering multiple myeloma: Final analyses of survival outcomes from the phase 3 **AQUILA** study	Dec. 12, 2026 10:15 – 10:30 AM
Abstract #0940	Comparative outcomes of active monitoring in high-risk smoldering multiple myeloma: Randomized **AQUILA study versus real-world SPARK** study	Dec. 14, 2026 3:30 – 3:45 PM
Poster Presentations		
Abstract #4008	Evaluation of peripheral blood (PB) and bone marrow (BM) minimal residual disease (MRD) techniques in patients with transplant-eligible (TE) newly diagnosed multiple myeloma (NDMM) treated with daratumumab, bortezomib, lenalidomide, and dexamethasone (D-VRd): Prospective Phase 2 **TAURUS** study	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #4020	Health-related quality of life in post-transplant patients with newly diagnosed multiple myeloma (NDMM) who received daratumumab plus lenalidomide versus lenalidomide alone as maintenance therapy in the **AURIGA** study	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #4028	Final efficacy and safety outcomes of subcutaneous daratumumab plus lenalidomide versus lenalidomide alone as maintenance therapy in newly diagnosed multiple myeloma (NDMM) after transplant: **AURIGA** study	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #4558	Real-world characteristics and outcomes of patients (pts) with newly diagnosed multiple myeloma (NDMM) receiving autologous stem cell transplantation (ASCT): a multi-country analysis from the **HONEUR** Network (2018–2024)	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #5783	Final minimal residual disease (MRD) dynamics analysis in patients with newly diagnosed multiple myeloma (NDMM) receiving subcutaneous daratumumab plus lenalidomide versus lenalidomide alone as post-transplant maintenance therapy in the **AURIGA** study	Dec. 14, 2026 6:00 – 8:00 PM

Johnson & Johnson-sponsored bleximenib studies

Abstract number	Title	Presentation time (CST)
Acute myeloid leukemia		
Oral Presentation		
Abstract #0661	A favorable benefit-risk profile of bleximenib in adults with relapsed/refractory (R/R) acute myeloid leukemia (AML) with *KMT2A* rearrangements or *NPM1* mutations: Topline results from the Phase 2 **cAMeLot-1** study	Dec. 13, 2026 4:30 – 4:45 PM
Poster Presentation		
Abstract #1639	Bleximenib population pharmacokinetics and exposure-response analyses from the phase 1/2 **cAMeLot-1** study	Dec. 12, 2026 5:30 – 7:30 PM

Johnson & Johnson-sponsored nipocalimab studies

Abstract number	Title	Presentation time (CST)
Warm autoimmune hemolytic anemia		
Poster Presentations		
Abstract #1107	Relationship between IgG levels and infection rates in nipocalimab-treated participants with warm autoimmune hemolytic anemia (wAIHA) in the Phase 2/3 ENERGY study	Dec. 12, 2026 5:30 – 7:30 PM
Abstract #1109	Nipocalimab for warm autoimmune hemolytic anemia: A subgroup analysis of the ENERGY study by patient- and disease-specific factors	Dec. 12, 2026 5:30 – 7:30 PM
Abstract #2866	Nipocalimab for warm autoimmune hemolytic anemia: Results from the open-label period of Phase 2/3 randomized, double-blind ENERGY study	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #4449	Health-related quality of life outcomes with nipocalimab in warm autoimmune hemolytic anemia: Results from the double-blind Phase 2/3 ENERGY study	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #4451	Humanistic burden of warm autoimmune hemolytic anemia from the physician and patient's perspective – results from a real-world survey	Dec. 13, 2026 6:00 – 8:00 PM
Abstract #4624	Pharmacodynamic effect of nipocalimab in warm autoimmune hemolytic anemia (wAIHA) and correlation with clinical improvement: Results from the ENERGY double-blind and open-label extension periods	Dec. 14, 2026 6:00 – 8:00 PM
Abstract #6209	Real-world clinical course of warm autoimmune hemolytic anemia: A global retrospective chart review	Dec. 14, 2026 6:00 – 8:00 PM
Abstract #6235	Association between fatigue and hemoglobin levels in patients with warm autoimmune hemolytic anemia: Results from a real-world survey	Dec. 14, 2026 6:00 – 8:00 PM

Johnson & Johnson-sponsored ciltacabtagene autoleucel studies

Abstract number	Title	Presentation time (CST)
Multiple myeloma		
Oral Presentations		
Abstract #0272	Absolute lymphocyte count based pre-emptive steroids decrease the risk of parkinsonism following ciltacabtagene autoleucel (Cilta-cel) in relapsed/refractory multiple myeloma (RRMM): First analysis from a multi-center observational study (**CITADEL**)	Dec. 12, 2026 2:15 – 2:30 PM
Abstract #0276	First report of durable survival outcomes with ciltacabtagene autoleucel (cilta-cel) in patients with daratumumab-refractory relapsed/refractory multiple myeloma: **CARTITUDE-4** subgroup analyses	Dec. 12, 2026 3:15 – 3:30 PM
Poster Presentations		
Abstract #2272	Tumor burden at ciltacabtagene autoleucel (cilta-cel) infusion as a predictor for clinical outcomes in patients (pts) with relapsed/refractory multiple myeloma (RRMM) in **CARTITUDE-4**	Dec. 12, 2026 5:30 – 7:30 PM
Abstract #2273	Real-world safety and effectiveness of early-line ciltacabtagene autoleucel (cilta-cel) in patients (pts) with relapsed/refractory multiple myeloma (RRMM) in Europe and Brazil – subgroup analysis of a prospective, noninterventional, post authorization safety study (**PASS**)	Dec. 12, 2026 5:30 – 7:30 PM

Johnson & Johnson-sponsored early assets studies

Abstract number	Title	Presentation time (CST)
Essential thrombocythemia		
Oral Presentation		
Abstract #1033	First data from Phase 1 study of safety and efficacy of JNJ-88549968, a mutant calreticulin (CALRmut) x CD3 T-cell engaging antibody for the treatment of essential thrombocythemia (ET)	Dec. 14, 2026 4:30 – 4:45 PM

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. In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors. Multiple myeloma is the second most common blood cancer worldwide. More than 180,000 new cases of multiple myeloma are diagnosed globally each year. People living with multiple myeloma have a 5-year survival rate of 59.8%. 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. In recent years, overall survival has improved from years to decades, with effective treatment options now available across every stage and line of therapy.

About acute myeloid leukemia

Acute myeloid leukemia (AML) is an aggressive, fast-growing blood cancer that originates in the bone marrow and is marked by the uncontrolled proliferation of immature white blood cells known as myeloblasts. These malignant cells crowd out healthy blood-forming cells, leading to complications such as anemia, infections and bleeding. Acute myeloid leukemia progresses rapidly, often requiring immediate treatment after diagnosis. It is the most common type of acute leukemia in adults, with a median age of diagnosis around 70 years. Despite treatment advances, acute myeloid leukemia remains associated with poor patient outcomes, particularly in older adults or those with high-risk genetic profiles. The five-year survival rate remains the lowest among leukemias, with outcomes especially poor in patients with relapsed or refractory KMT2Ar or NPM1m disease, where survival can be as short as 2 to 3 months after a second relapse – highlighting a significant unmet medical need.

About warm autoimmune hemolytic anemia

Warm autoimmune hemolytic anemia (wAIHA) is a rare, life-threatening condition where autoantibodies attach to and destroy red blood cells (RBCs), resulting in anemia. Approximately 1-3 new people per 100,000 are affected by wAIHA per year, and about 1 in 8,000 individuals are living with the condition. This condition affects both women and men and can affect people at any age, with incidence increasing over the age of 50. Additionally, people with wAIHA are at increased risk of other serious complications such as venous thrombotic events, acute renal failure, and infection.

About essential thrombocythemia

Essential thrombocythemia (ET) is a rare, chronic blood cancer characterized by the overproduction of platelets in the bone marrow, increasing the risk of blood clots, bleeding and other complications, including progression to myelofibrosis and, more rarely, acute leukemia. ET is a type of myeloproliferative neoplasm (MPN) driven by acquired genetic mutations, including mutations in the calreticulin (*CALR*) gene. While current treatments primarily focus on managing blood counts and reducing the risk of complications, patients may face lifelong treatment burdens and the potential for disease progression, underscoring the need for novel targeted therapies that address the underlying drivers of disease.

About TECVAYLI® (teclistamab-cqyv)

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.

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 35,000 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 TALVEY® (talquetamab-tgvs)

TALVEY® is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and G protein-coupled receptor class C group 5 member D (GPRC5D), a novel multiple myeloma target which is highly expressed on the surface of multiple myeloma cells and nonmalignant plasma cells, as well as some healthy tissues such as epithelial cells of the skin and tongue.

TALVEY® (talquetamab-tgvs) received accelerated approval from the U.S. FDA in August 2023 as a first-in-class GPRC5D-targeting bispecific antibody 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 antibody. The European Commission (EC) granted conditional marketing authorization (CMA) of TALVEY® (talquetamab-tgvs) in August 2023 as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. Since FDA approval, more than 15,200 patients have been treated with TALVEY®.

About ramantamig (JNJ-79635322)

Ramantamig is an investigational trispecific antibody designed to target two clinically validated myeloma antigens, B-cell maturation antigen (BCMA) and G protein-coupled receptor class C group 5 member D (GPRC5D), while engaging CD3 on T cells in a single molecule. It builds on Johnson & Johnson's experience with BCMA- and GPRC5D-targeting bispecific antibodies. Ramantamig is being evaluated across a broad clinical development program, including TRIlogy, which comprises Phase 3 studies in relapsed or refractory and newly diagnosed multiple myeloma. Ramantamig is the first trispecific antibody to enter Phase 3 development in multiple myeloma. Its safety and efficacy have not been established for any approved indication.

About DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) and DARZALEX® (daratumumab)

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) received U.S. FDA approval in May 2020 and is approved for 12 indications in multiple myeloma, five of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible. DARZALEX *FASPRO*® is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. 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® (daratumumab) received U.S. FDA approval in November 2015 and is approved in eight indications, three of which are in the frontline setting, including newly diagnosed patients who are transplant-eligible and ineligible.

DARZALEX® is the first CD38-directed antibody approved to treat multiple myeloma. DARZALEX®-based regimens have been used in the treatment of more than 865,000 patients worldwide.

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

For more information, visit www.DARZALEX.com.

About bleximenib (JNJ-75276617)

Bleximenib is an investigational oral menin inhibitor being evaluated for the treatment of patients with newly diagnosed and relapsed or refractory AML. It targets a key oncogenic interaction between menin and KMT2A proteins, disrupting a pathway that drives leukemic cell growth in patients with *KMT2A gene rearrangements* or *NPM1 gene mutations*. Bleximenib is currently being investigated in Phase 1, 2, and 3 clinical trials, either as a monotherapy or in combination with AML-directed therapies to further explore its potential in both relapsed or refractory and newly diagnosed AML settings. The U.S. FDA has granted bleximenib two BTDs for the treatment of adults living with R/R *KMT2A*-rearranged and *NPM1*-mutated AML.

About IMAAVY® (nipocalimab-aahu)

IMAAVY® is an immunoselective treatment designed to target, bind with high affinity, and block the neonatal Fc receptor (FcRn), reducing circulating immunoglobulin G (IgG) antibodies that drive disease while also preserving B-cell function based on in vitro and/or in vivo studies. IMAAVY® is currently approved for the treatment of generalized myasthenia gravis (gMG) in adults and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. IMAAVY® is also approved for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids.

Nipocalimab is being investigated across three key segments in the autoantibody space including Rheumatologic diseases, Rare Autoantibody diseases, and Maternal Fetal diseases mediated by maternal alloantibodies, in which blockade of IgG binding to FcRn in the placenta is believed to limit transplacental transfer of maternal alloantibodies to the fetus.

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted several key designations to nipocalimab including:

- EU EMA Orphan medicinal product designation for hemolytic disease of the fetus and newborn (HDFN) in October 2019 and fetal and neonatal alloimmune thrombocytopenia (FNAIT) in April 2025.
- U.S. FDA Fast Track designation in HDFN, and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021, FNAIT in March 2024, Sjögren's disease (SjD) in March 2025, and systemic lupus erythematosus (SLE) in January 2026.
- U.S. FDA Orphan drug status for wAIHA in December 2019, HDFN in June 2020, gMG in February 2021, chronic inflammatory demyelinating polyneuropathy (CIDP) in October 2021 and FNAIT in December 2023.
- U.S. FDA Breakthrough Therapy Designation for HDFN in February 2024 and for SjD in November 2024.
- U.S. FDA granted Priority Review in gMG in Q4 2024 and wAIHA in Q2 2026.

The legal manufacturer for IMAAVY® is Janssen Biotech, Inc.

About CARVYKTI® (ciltacabtagene autoleucel; cilta-cel)

CARVYKTI® (cilta-cel) received U.S. Food and Drug Administration approval in February 2022 for the treatment of adults with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

In April 2024, CARVYKTI® was approved in the U.S. for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor, an immunomodulatory agent, and who are refractory to lenalidomide, following a unanimous (11 to 0) FDA Oncologic Drugs Advisory Committee (ODAC) recommendation in support of this new indication. In April 2024, the European Medicines Agency (EMA) approved a Type II variation for CARVYKTI® for the treatment of adults with relapsed and refractory multiple myeloma who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide. In September 2022, Japan's Ministry of Health, Labour and Welfare (MHLW) approved CARVYKTI® for the treatment of adults with relapsed or refractory multiple myeloma in patients that have no history of CAR-positive T cell infusion therapy targeting BCMA and who have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy. In July 2026, CARVYKTI® obtained a label expansion in Japan, allowing its use in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

CARVYKTI® is a BCMA-directed, autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding chimeric antigen receptor (CAR) that directs the CAR-positive T cells to eliminate cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B cells and plasma cells. The CARVYKTI® CAR protein features two BCMA-targeting single domains designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells. CARVYKTI® is available in 17 markets worldwide and has been used to treat more than 15,000 patients globally.

In December 2017, Janssen Biotech, Inc., a Johnson & Johnson company, entered into an exclusive worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialize CARVYKTI®.

For more information, visit www.CARVYKTI.com.

About JNJ-88549968

JNJ-88549968 is an investigational bispecific T-cell engaging antibody being evaluated for the treatment of patients with essential thrombocythemia (ET) whose disease is driven by mutations in the calreticulin (*CALR*) gene. It binds to mutant calreticulin (CALRmut) on the surface of malignant cells and to CD3 on T cells, directing the immune system to recognize and eliminate the cells that drive the disease. JNJ-88549968 is currently being investigated in a Phase 1 clinical study. The U.S. FDA granted JNJ-88549968 Breakthrough Therapy Designation for the treatment of adult patients with ET who have a *CALR* mutation, and EMA granted it Priority Medicines (PRIME) designation for the treatment of adults with *CALR*-mutated ET. The U.S. FDA has also granted JNJ-88549968 Orphan Drug Designation for ET.

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 (≥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 (≥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 (≥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.

TALVEY® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is 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 and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a 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 TALVEY®. Initiate TALVEY® treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Recurrent CRS occurred in 30% of patients. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic Toxicity including ICANS: TALVEY® can cause serious, life-threatening neurologic toxicity or fatal neurologic toxicity, including ICANS.

In the clinical trial, neurologic toxicity, including ICANS, occurred in 55% of patients who received the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction, including ataxia/cerebellar ataxia (10%). ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment and treat promptly. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity. Withhold or permanently discontinue TALVEY® based on severity and consider further management per current practice guidelines [see Dosage and Administration (2.5)].

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

TECVAYLI® and TALVEY® REMS: TALVEY® 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.

Further information about the TECVAYLI® and TALVEY® REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

Oral Toxicity and Weight Loss: TALVEY® can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis.

In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss, regardless of having an oral toxicity, including 29% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY® or permanently discontinue based on severity.

Infections: TALVEY® can cause infections, including life-threatening or fatal infections.

In the clinical trial, serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis, and COVID-19 (2.7%).

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

Cytopenias: TALVEY® can cause cytopenias, including neutropenia and thrombocytopenia.

In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY®. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY® as recommended based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash.

In the clinical trial, skin reactions occurred in 62% of patients, with Grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to Grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY® as recommended based on severity.

Hepatotoxicity: TALVEY® can cause hepatotoxicity. Elevated ALT occurred in 33% of patients, with Grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with Grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY® or consider permanent discontinuation of TALVEY® based on severity [see Dosage and Administration (2.5)].

Embryo-Fetal Toxicity: Based on its mechanism of action, TALVEY® 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 TALVEY® and for 3 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

The most common Grade 3 or 4 laboratory abnormalities (≥30%) are lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

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

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=1253) 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 ≥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 (≥40%) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

DARZALEX *FASPRO*®: ADVERSE REACTIONS
In multiple myeloma, the most common adverse reaction (≥20%) with DARZALEX *FASPRO*® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, sleep disorder, headache, rash, renal impairment, motor dysfunction, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, decreased appetite, urinary tract infection, abdominal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, dizziness, bruising, and COVID-19.

The most common hematologic laboratory abnormalities (≥40%) with DARZALEX *FASPRO*® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

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

IMAAVY® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

IMAAVY® is a neonatal Fc receptor blocker indicated for the treatment of:

- generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
- warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMAAVY®?
IMAAVY® is a prescription medicine that may cause serious side effects, including:

- **Infections.** IMAAVY® may increase your risk of infections, including serious infections. If you have an infection, your healthcare provider will treat your infection or delay your infusion until your infection is gone. Tell your healthcare provider right away if you have any of the following infection symptoms:
  - fever
  - chills
  - shivering
  - cough
  - sore throat
  - fever blisters
  - burning when you urinate
  - trouble breathing
- **Allergic (hypersensitivity) reactions** can happen during or up to a few weeks after your IMAAVY® infusion. Tell your healthcare provider and get emergency medical help right away if you get any of these symptoms during or after your IMAAVY® infusion:
  - a swollen face, lips, mouth, tongue, or throat
  - trouble swallowing or breathing
  - hives
  - itchy rash
  - chest pain or tightness
- **Infusion-related reactions**. Tell your healthcare provider right away if you get any of these symptoms during or within a few days after your IMAAVY® infusion:
  - headache
  - rash
  - nausea
  - fatigue
  - dizziness
  - chills
  - flu-like symptoms
  - redness of skin

Do not receive IMAAVY® if you have a history of a severe allergic reaction to nipocalimab-aahu or any of the ingredients in IMAAVY®. Reactions have included angioedema and anaphylaxis. Refer to the Patient Information section of the Prescribing Information for a complete list of ingredients in IMAAVY®.

Before receiving IMAAVY®, tell your healthcare provider about all of your medical conditions, including if you:

- have had an allergic reaction to IMAAVY®.
- have or had any recent infections or symptoms of infection.
- have or had shingles (herpes zoster) or mono (mononucleosis caused by Epstein-Barr virus).
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMAAVY® should not receive live vaccines.
- are pregnant or plan to become pregnant. It is not known if IMAAVY® will harm your unborn baby.

Pregnancy Safety Study. There is a pregnancy safety study for IMAAVY®. If IMAAVY® is given during pregnancy or you become pregnant while receiving IMAAVY®, your healthcare provider should report IMAAVY® exposure by contacting Janssen at 1-800-526-7736.

- are breastfeeding or plan to breastfeed. IMAAVY® can pass into your breast milk. It is not known if IMAAVY® will harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with IMAAVY®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of IMAAVY®?
IMAAVY® may cause serious side effects. See "What is the most important information I should know about IMAAVY®?"

The most common side effects in people with gMG treated with IMAAVY® include: respiratory tract infection, peripheral edema (swelling in your hands, ankles, or feet), and muscle spasms.

The most common side effects in people with wAIHA treated with IMAAVY® include: peripheral edema (swelling in your hands, ankles, or feet), diarrhea, and pyrexia (fever).

These are not all the possible side effects of IMAAVY®. Call your doctor for medical advice about side effects. **You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.**

Please see the full Prescribing Information and Patient Information for IMAAVY® and discuss any questions you have with your doctor.

Dosage Form and Strengths: IMAAVY® is supplied as a 300 mg/1.62 mL and a 1,200 mg/6.5 mL (185 mg/mL) single-dose vial per carton for intravenous injection.

CARVYKTI® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

CARVYKTI® is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED and RECURRENT CYTOPENIA, and SECONDARY HEMATOLOGICAL MALIGNANCIES Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI®. Provide supportive care and/or corticosteroids as needed. Parkinsonism and Guillain-Barré syndrome (GBS) and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI®. Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI®. HLH/MAS can occur with CRS or neurologic toxicities. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI®. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life threatening reactions, occurred following treatment with CARVYKTI®. Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred in patients following treatment with CARVYKTI®. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®.

WARNINGS AND PRECAUTIONS

Increased early mortality. In CARTITUDE-4, a (1:1) randomized controlled trial, there was a numerically higher percentage of early deaths in patients randomized to the CARVYKTI® treatment arm compared to the control arm. Among patients with deaths occurring within the first 10 months from randomization, a greater proportion (29/208; 14%) occurred in the CARVYKTI® arm compared to (25/211; 12%) in the control arm. Of the 29 deaths that occurred in the CARVYKTI® arm within the first 10 months of randomization, 10 deaths occurred prior to CARVYKTI® infusion, and 19 deaths occurred after CARVYKTI® infusion. Of the 10 deaths that occurred prior to CARVYKTI® infusion, all occurred due to disease progression, and none occurred due to adverse events. Of the 19 deaths that occurred after CARVYKTI® infusion, 3 occurred due to disease progression, and 16 occurred due to adverse events. The most common adverse events were due to infection (n=12).

Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® for RRMM in the CARTITUDE-1 & -4 studies (N=285), CRS occurred in 84% (238/285), including ≥ Grade 3 CRS (ASTCT 2019) in 4% (11/285) of patients. Median time to onset of CRS, any grade, was 7 days (range: 1 to 23 days). CRS resolved in 82% with a median duration of 4 days (range: 1 to 97 days). The most common manifestations of CRS in all patients combined (≥10%) included fever (84%), hypotension (29%) and aspartate aminotransferase increased (11%). Serious events that may be associated with CRS include pyrexia, hemophagocytic lymphohistiocytosis, respiratory failure, disseminated intravascular coagulation, capillary leak syndrome, and supraventricular and ventricular tachycardia. CRS occurred in 78% of patients in CARTITUDE-4 (3% Grade 3 to 4) and in 95% of patients in CARTITUDE-1 (4% Grade 3 to 4).

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. HLH/MAS is a potentially life threatening condition. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Confirm that a minimum of 2 doses of tocilizumab are available prior to infusion of CARVYKTI®.

Of the 285 patients who received CARVYKTI® in clinical trials, 53% (150/285) patients received tocilizumab; 35% (100/285) received a single dose, while 18% (50/285) received more than 1 dose of tocilizumab. Overall, 14% (39/285) of patients received at least 1 dose of corticosteroids for treatment of CRS.

Monitor patients at least daily for 7 days following CARVYKTI® infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 2 weeks after infusion. At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic toxicities, which may be severe, life-threatening, or fatal, occurred following treatment with CARVYKTI®. Neurologic toxicities included ICANS, neurologic toxicity with signs and symptoms of Parkinsonism, GBS, immune mediated myelitis, peripheral neuropathies, and cranial nerve palsies. Counsel patients on the signs and symptoms of these neurologic toxicities, and on the delayed nature of onset of some of these toxicities. Instruct patients to seek immediate medical attention for further assessment and management if signs or symptoms of any of these neurologic toxicities occur at any time.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies for RRMM, one or more neurologic toxicities occurred in 24% (69/285), including ≥ Grade 3 cases in 7% (19/285) of patients. Median time to onset was 10 days (range: 1 to 101) with 63/69 (91%) of cases developing by 30 days. Neurologic toxicities resolved in 72% (50/69) of patients with a median duration to resolution of 23 days (range: 1 to 544). Of patients developing neurotoxicity, 96% (66/69) also developed CRS. Subtypes of neurologic toxicities included ICANS in 13%, peripheral neuropathy in 7%, cranial nerve palsy in 7%, parkinsonism in 3%, and immune mediated myelitis in 0.4% of the patients.

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS): Patients receiving CARVYKTI® may experience fatal or life-threatening ICANS following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, ICANS occurred in 13% (36/285), including Grade ≥3 in 2% (6/285) of the patients. Median time to onset of ICANS was 8 days (range: 1 to 28 days). ICANS resolved in 30 of 36 (83%) of patients, with a median time to resolution of 3 days (range: 1 to 143 days). Median duration of ICANS was 6 days (range: 1 to 1229 days) in all patients, including those with ongoing neurologic events at the time of death or data cutoff. Of patients with ICANS, 97% (35/36) had CRS. The onset of ICANS occurred during CRS in 69% of patients, before and after the onset of CRS in 14% of patients, respectively.

Immune Effector Cell-associated Neurotoxicity Syndrome occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3) and in 23% of patients in CARTITUDE-1 (3% Grade 3). The most frequent (≥2%) manifestations of ICANS included encephalopathy (12%), aphasia (4%), headache (3%), motor dysfunction (3%), ataxia (2%), and sleep disorder (2%). Monitor patients at least daily for 7 days following CARVYKTI® infusion for signs and symptoms of ICANS. Rule out other causes of ICANS symptoms.

Monitor patients for signs or symptoms of ICANS for at least 2 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed. Advise patients to avoid driving for at least 2 weeks following infusion.

Parkinsonism: Neurologic toxicity with parkinsonism has been reported in clinical trials of CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, parkinsonism occurred in 3% (8/285), including Grade ≥3 in 2% (5/285) of the patients. Median time to onset of parkinsonism was 56 days (range: 14 to 914 days). Parkinsonism resolved in 1 of 8 (13%) of patients with a median time to resolution of 523 days. Median duration of parkinsonism was 243.5 days (range: 62 to 720 days) in all patients, including those with ongoing neurologic events at the time of death or data cutoff. The onset of parkinsonism occurred after CRS for all patients and after ICANS for 6 patients.

Parkinsonism occurred in 1% of patients in CARTITUDE-4 (no Grade 3 to 4) and in 6% of patients in CARTITUDE-1 (4% Grade 3 to 4).

Manifestations of parkinsonism included movement disorders, cognitive impairment, and personality changes. Monitor patients for signs and symptoms of parkinsonism that may be delayed in onset and managed with supportive care measures. There is limited efficacy information with medications used for the treatment of Parkinson's disease for the improvement or resolution of parkinsonism symptoms following CARVYKTI® treatment.

Guillain-Barré syndrome: A fatal outcome following GBS occurred following treatment with CARVYKTI® despite treatment with intravenous immunoglobulins. Symptoms reported include those consistent with Miller-Fisher variant of GBS, encephalopathy, motor weakness, speech disturbances, and polyradiculoneuritis.

Monitor for GBS. Evaluate patients presenting with peripheral neuropathy for GBS. Consider treatment of GBS with supportive care measures and in conjunction with immunoglobulins and plasma exchange, depending on severity of GBS.

Immune mediated myelitis: Grade 3 myelitis occurred 25 days following treatment with CARVYKTI® in CARTITUDE-4 in a patient who received CARVYKTI® as subsequent therapy. Symptoms reported included hypoesthesia of the lower extremities and the lower abdomen with impaired sphincter control. Symptoms improved with the use of corticosteroids and intravenous immune globulin. Myelitis was ongoing at the time of death from other cause.

Peripheral neuropathy occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, peripheral neuropathy occurred in 7% (21/285), including Grade ≥3 in 1% (3/285) of the patients. Median time to onset of peripheral neuropathy was 57 days (range: 1 to 914 days). Peripheral neuropathy resolved in 11 of 21 (52%) of patients with a median time to resolution of 58 days (range: 1 to 215 days). Median duration of peripheral neuropathy was 149.5 days (range: 1 to 692 days) in all patients including those with ongoing neurologic events at the time of death or data cutoff.

Peripheral neuropathies occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3 to 4) and in 7% of patients in CARTITUDE-1 (2% Grade 3 to 4). Monitor patients for signs and symptoms of peripheral neuropathies. Patients who experience peripheral neuropathy may also experience cranial nerve palsies or GBS.

Cranial nerve palsies occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, cranial nerve palsies occurred in 7% (19/285), including Grade ≥3 in 1% (1/285) of the patients. Median time to onset of cranial nerve palsies was 21 days (range: 17 to 101 days). Cranial nerve palsies resolved in 17 of 19 (89%) of patients with a median time to resolution of 66 days (range: 1 to 209 days). Median duration of cranial nerve palsies was 70 days (range: 1 to 262 days) in all patients, including those with ongoing neurologic events at the time of death or data cutoff. Cranial nerve palsies occurred in 9% of patients in CARTITUDE-4 (1% Grade 3 to 4) and in 3% of patients in CARTITUDE-1 (1% Grade 3 to 4).

The most frequent cranial nerve affected was the 7th cranial nerve. Additionally, cranial nerves III, V, and VI have been reported to be affected.

Monitor patients for signs and symptoms of cranial nerve palsies. Consider management with systemic corticosteroids, depending on the severity and progression of signs and symptoms.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, HLH/MAS occurred in 1% (3/285) of patients. All events of HLH/MAS had onset within 99 days of receiving CARVYKTI®, with a median onset of 10 days (range: 8 to 99 days), and all occurred in the setting of ongoing or worsening CRS. The manifestations of HLH/MAS included hyperferritinemia, hypotension, hypoxia with diffuse alveolar damage, coagulopathy and hemorrhage, cytopenia, and multi-organ dysfunction, including renal dysfunction and respiratory failure.

Patients who develop HLH/MAS have an increased risk of severe bleeding. Monitor hematologic parameters in patients with HLH/MAS and transfuse per institutional guidelines. Fatal cases of HLH/MAS occurred following treatment with CARVYKTI®.

HLH is a life-threatening condition with a high mortality rate if not recognized and treated early. Treatment of HLH/MAS should be administered per institutional standards.

Prolonged and Recurrent Cytopenias: Patients may exhibit prolonged and recurrent cytopenias following lymphodepleting chemotherapy and CARVYKTI® infusion.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, Grade 3 or higher cytopenias not resolved by Day 30 following CARVYKTI® infusion occurred in 62% (176/285) of the patients and included thrombocytopenia 33% (94/285), neutropenia 27% (76/285), lymphopenia 24% (67/285), and anemia 2% (6/285). After Day 60 following CARVYKTI® infusion, 22%, 20%, 5%, and 6% of patients had a recurrence of Grade 3 or 4 lymphopenia, neutropenia, thrombocytopenia, and anemia, respectively, after initial recovery of their Grade 3 or 4 cytopenia. Seventy-seven percent (219/285) of patients had one, two, or three or more recurrences of Grade 3 or 4 cytopenias after initial recovery of Grade 3 or 4 cytopenia. Sixteen and 25 patients had Grade 3 or 4 neutropenia and thrombocytopenia, respectively, at the time of death.

Monitor blood counts prior to and after CARVYKTI® infusion. Manage cytopenias with growth factors and blood product transfusion support according to local institutional guidelines.

Infections: CARVYKTI® should not be administered to patients with active infection or inflammatory disorders. Severe, life-threatening, or fatal infections occurred in patients after CARVYKTI® infusion.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, infections occurred in 57% (163/285), including Grade ≥3 in 24% (69/285) of patients. Grade 3 or 4 infections with an unspecified pathogen occurred in 12%, viral infections in 6%, bacterial infections in 5%, and fungal infections in 1% of patients. Overall, 5% (13/285) of patients had Grade 5 infections, 2.5% of which were due to COVID-19. Patients treated with CARVYKTI® had an increased rate of fatal COVID-19 infections compared to the standard therapy arm.

Monitor patients for signs and symptoms of infection before and after CARVYKTI® infusion and treat patients appropriately. Administer prophylactic, pre-emptive, and/or therapeutic antimicrobials according to the standard institutional guidelines. Febrile neutropenia was observed in 5% of patients after CARVYKTI® infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care, as medically indicated. Counsel patients on the importance of prevention measures. Follow institutional guidelines for the vaccination and management of immunocompromised patients with COVID-19.

Viral Reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients with hypogammaglobulinemia. Perform screening for Cytomegalovirus (CMV), HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) or any other infectious agents if clinically indicated in accordance with clinical guidelines before collection of cells for manufacturing. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/clinical practice.

Reactivation of John Cunningham (JC) virus, leading to progressive multifocal leukoencephalopathy (PML), including cases with fatal outcomes, have been reported following treatment. Perform appropriate diagnostic evaluations in patients with neurological adverse events.

Hypogammaglobulinemia can occur in patients receiving treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, hypogammaglobulinemia adverse event was reported in 36% (102/285) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 93% (265/285) of patients. Hypogammaglobulinemia either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion occurred in 94% (267/285) of patients treated. Fifty-six percent (161/285) of patients received intravenous immunoglobulin (IVIG) post CARVYKTI® for either an adverse reaction or prophylaxis. Monitor immunoglobulin levels after treatment with CARVYKTI® and administer IVIG for IgG <400 mg/dL. Manage per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.
Use of Live Vaccines: The safety of immunization with live viral vaccines during or following CARVYKTI® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during CARVYKTI® treatment, and until immune recovery following treatment with CARVYKTI®.

Hypersensitivity Reactions occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, hypersensitivity reactions occurred in 5% (13/285), all of which were ≤2 Grade. Manifestations of hypersensitivity reactions included flushing, chest discomfort, tachycardia, wheezing, tremor, burning sensation, non-cardiac chest pain, and pyrexia.

Serious hypersensitivity reactions, including anaphylaxis, may be due to the dimethyl sulfoxide (DMSO) in CARVYKTI®. Patients should be carefully monitored for 2 hours after infusion for signs and symptoms of severe reaction. Treat promptly and manage patients appropriately according to the severity of the hypersensitivity reaction.

Immune effector cell-associated enterocolitis (IEC-EC) has occurred in patients treated with CARVYKTI®. Manifestations include severe or prolonged diarrhea, abdominal pain, and weight loss requiring parenteral nutrition. IEC-EC has been associated with fatal outcome from perforation or sepsis. Manage according to institutional guidelines, including referral to gastroenterology and infectious disease specialists.

In cases of refractory IEC-EC, consider additional workup to exclude alternative etiologies, including T-cell lymphoma of the GI tract, which has been reported in the post marketing setting.

Secondary Malignancies: Patients treated with CARVYKTI® may develop secondary malignancies. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, myeloid neoplasms occurred in 5% (13/285) of patients (9 cases of myelodysplastic syndrome, 3 cases of acute myeloid leukemia, and 1 case of myelodysplastic syndrome followed by acute myeloid leukemia). The median time to onset of myeloid neoplasms was 447 days (range: 56 to 870 days) after treatment with CARVYKTI®. Ten of these 13 patients died following the development of myeloid neoplasms; 2 of the 13 cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy. Cases of myelodysplastic syndrome and acute myeloid leukemia have also been reported in the post marketing setting. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®. Mature T-cell malignancies, including CAR positive tumors, may present as soon as weeks following infusions, and may include fatal outcomes.

Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Janssen Biotech, Inc., at 1-800-526-7736 for reporting and to obtain instructions on collection of patient samples.

ADVERSE REACTIONS

The most common nonlaboratory adverse reactions (incidence greater than 20%) are pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogen unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting. The most common Grade 3 or 4 laboratory adverse reactions (incidence greater than or equal to 50%) include lymphopenia, neutropenia, white blood cell decreased, thrombocytopenia, and anemia.

Please read full Prescribing Information, including Boxed Warning, for CARVYKTI®.

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.jnj.com/innovativemedicine/ Follow us at @JNJInnovMed. Janssen Research & Development, LLC, and Janssen Biotech, Inc., are both Johnson & Johnson companies.

Caution 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 of TECVAYLI® (teclistamab), TALVEY® (talquetamab), ramantamig (JNJ-79635322), DARZALEX FASPRO® *(daratumumab), bleximenib (JNJ-75276617), IMAAVY® (nipocalimab-aahu), CARVYKTI® (ciltacabtagene autoleucel; cilta-cel)* and *JNJ-88549968. 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 actions; 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.*