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NEWS RELEASE

Johnson & Johnson to showcase strength of its broad hematology portfolio and pipeline at the 2024 American Society of Hematology Annual Meeting

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More than 90 presentations of clinical trial and real-world data highlight potentially practice-changing evidence and commitment to pioneer the next wave of therapies for patients with hematologic malignancies

RARITAN, N.J., Nov. 19, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) announced today more than 90 abstracts featuring data from the Company's differentiated blood cancer portfolio and pipeline will be presented at the 66th American Society of Hematology (ASH) Annual Meeting in San Diego from December 7-10. Clinical trial and real-world data will highlight the Company's broad and expanding portfolio of hematologic therapies, deepening its leadership in novel approaches to treat multiple myeloma as well as myeloid and B-cell malignancies. Six additional abstracts focus on the Company's commitment and patient insights in warm autoimmune hemolytic anemia (wAIHA), a rare autoantibody-driven disease, and fetal and neonatal alloimmune thrombocytopenia (FNAIT), an alloimmune disorder of pregnancy.

"This year's data line-up at ASH highlights our unwavering commitment to transform outcomes for patients with hematologic malignancies," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. "Our relentless pursuit to provide each person diagnosed with blood cancer with treatment options at every stage of their disease inspires us to continue driving innovation in this space."

"The breadth of scientific evidence being presented at ASH speaks to our drive to deliver life-changing treatments for patients with blood cancer," said June Lanoue, U.S. President, Hematology, Johnson & Johnson Innovative Medicine. "We look forward to highlighting the latest clinical trial and real-world data that demonstrate how we are

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addressing unmet needs for these patients."

New data highlight progress across all treatment stages of multiple myeloma, including differentiated and promising combination regimens

Key clinical and real-world studies focus on providing healthcare professionals with important data that may help better inform their choice of treatment regimens for patients, including:

- Phase 3 Randomized Study of DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj) Monotherapy Versus Active Monitoring in Patients with High-Risk Smoldering Multiple Myeloma: Primary Results of the AQUILA Study (Oral #733)
- Phase 3 Randomized Study of DARZALEX FASPRO[®] + Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus VRd Alone in Patients with Transplant-Ineligible Newly Diagnosed Multiple Myeloma or for Whom Transplant is Not Planned as Initial Therapy: Analysis of Minimal Residual Disease in the CEPHEUS Trial (Oral #362)
- DARZALEX FASPRO[®] Plus Lenalidomide Versus Lenalidomide Alone as Maintenance Therapy in Newly Diagnosed Multiple Myeloma After Transplant: Analysis of the Phase 3 AURIGA Study Among Clinically Relevant Subgroups (Oral #654)
- Subcutaneous DARZALEX FASPRO[®] + Bortezomib, Cyclophosphamide, and Dexamethasone (VCD) in Patients with Newly Diagnosed Light Chain Amyloidosis: Overall Survival and Final Major Organ Deterioration Progression-Free Survival Results from the Phase 3 ANDROMEDA Study (Oral #891)
- CARVYKTI[®] (ciltacabtagene autoleucel; cilta-cel) vs Standard of Care in Patients with Lenalidomide-Refractory Multiple Myeloma After 1–3 Lines of Therapy: Minimal Residual Disease Negativity in the Phase 3 CARTITUDE-4 Trial (Oral #1032)
- Phase 3 Study of TECVAYLI[®] (teclistamab-cqyv) in Combination with Lenalidomide and TECVAYLI[®] Alone
 Versus Lenalidomide Alone in Newly Diagnosed Multiple Myeloma as Maintenance Therapy Following
 Autologous Stem Cell Transplantation: Safety Run-in Results from the MajesTEC-4/EMN30 Trial (Oral #494)
- Phase 2 Study of TECVAYLI[®]-Based Induction Regimens in Patients with Transplant-eligible Newly Diagnosed Multiple Myeloma: Results From the GMMG-HD10/DSMM-XX (MajesTEC-5) Trial (Oral #493)
- Pharmacodynamic Signatures and Correlatives of Response in Patients with Relapsed/Refractory Multiple Myeloma Treated with TALVEY[®] (talquetamab-tgvs) or TECVAYLI[®] Plus DARZALEX[®] (daratumumab) and Pomalidomide (Oral #594)

Continued clinical innovation in treatment of B-cell malignancies to be shown through new and updated data

Ongoing studies of IMBRUVICA[®] (ibrutinib) fixed-duration combination provide an opportunity to demonstrate long-term benefits of IMBRUVICA[®] in chronic lymphocytic leukemia. Key presentations:

- First-Line IMBRUVICA[®] Plus Venetoclax vs Chlorambucil Plus Obinutuzumab in Elderly or Comorbid Patients with Chronic Lymphocytic Leukemia: GLOW Study 64-Month Follow-Up and Adverse Event-Free Progression-Free Survival Analysis (Poster #1871)
- Consistently High 5.5-Year Progression-Free Survival Rates in Patients with and without Bulky Baseline
 Lymphadenopathy ≥5 cm are Associated with High Undetectable Minimal Residual Disease (uMRD4) Rates
 After First-Line Treatment with Fixed-Duration Ibrutinib + Venetoclax for Chronic Lymphocytic Leukemia/Small
 Lymphocytic Lymphoma in the Phase 2 CAPTIVATE Study (Poster #1869)
- Initiating First-Line Fixed-Duration IMBRUVICA[®] and Venetoclax in Patients with Chronic Lymphocytic Leukemia Improves Overall Survival Outcomes to Rates Approximating an Age-Matched General European Population (Poster #3254)

A suite of oral presentations from independent investigators will further inform the clinical understanding and application of IMBRUVICA[®] in chronic lymphocytic leukemia, as well as its potential in the treatment of previously untreated mantle cell lymphoma.

Phase 1 program for the menin inhibitor bleximenib demonstrates commitment to addressing unmet needs in acute myeloid leukemia for patients with both KMT2Ar and NPM1m alterations

Johnson & Johnson is investigating new targets with a focus on unmet needs in myeloid malignancies. Data will be presented from the Company's lead asset for the treatment of acute myeloid leukemia in both newly diagnosed and relapsed/refractory patients:

- Phase 1b Study of Menin-KMT2A Inhibitor Bleximenib in Combination with Intensive Chemotherapy in Newly Diagnosed Acute Myeloid Leukemia with KMT2Ar or NPM1 Alterations (Oral #215)
- Bleximenib Dose Optimization and Determination of RP2D From a Phase 1 Study in Relapsed/Refractory Acute Leukemia Patients with KMT2A and NPM1 Alterations (Oral #212)

Research showcases unmet need in hematologic allo- and autoantibody-driven diseases including wAIHA and FNAIT

Johnson & Johnson studies on the lived experience of patients and utilization of health resources in people living with wAIHA highlight the hardship faced by those impacted by the disease and need for research into investigational treatment options that may offer sustained disease control and minimize disease exacerbations. Additionally, an overview of an ongoing Phase 3 FNAIT clinical study design will be shared.

- Health Resource Utilization Among Patients with Warm Autoimmune Hemolytic Anemia in Sweden: A Retrospective Registry-Based Study (Poster #2255)
- A Retrospective Database Analysis of Healthcare Resource Utilization in Patients with Warm Autoimmune

Hemolytic Anemia in the United States (Poster #2324)

- Sentiment analysis applied to digital conversations among Warm Autoimmune Hemolytic Anemia patients receiving rituximab and/or blood transfusion (Poster #3705)
- Design of a Phase 3, Multicenter, Randomized, Open-Label Study of Nipocalimab or IVIG in Pregnancies at Risk for Fetal and Neonatal Alloimmune Thrombocytopenia (FREESIA-3) (Poster #1193.1)
- Insights on the Lived Experience of Warm Autoimmune Hemolytic Anemia from an Ongoing Patient Council (Online Only)
- Qualitative Examination of Treatment Experiences Among Individuals Living with Warm Autoimmune Hemolytic Anemia (Online Only)

Information on Johnson & Johnson sponsored abstracts is available on JNJ.com.

About multiple myeloma

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.¹ In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors.² Multiple myeloma is the third most common blood cancer worldwide and remains an incurable disease.³ In 2024, it was estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 people would die from the disease.⁴ People living with multiple myeloma have a 5-year survival rate of 59.8 percent.⁵ 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.^{6,7}

About smoldering multiple myeloma

Smoldering multiple myeloma is an asymptomatic precursor state to multiple myeloma (MM). Patients with SMM have higher levels of abnormal plasma cells in the bone marrow and an elevated monoclonal protein (M-protein) level in the blood, but they do not yet exhibit the symptoms commonly associated with active multiple myeloma, particularly end-organ damage. Fifteen percent of all cases of newly diagnosed multiple myeloma are classified as smoldering multiple myeloma, and half of those diagnosed with high-risk disease will progress to active multiple myeloma within two years.⁸

About warm autoimmune hemolytic anemia

Warm autoimmune hemolytic anemia (wAIHA) is a rare, life-threatening condition where autoantibodies lead to the premature destruction of red blood cells (RBCs), resulting in anemia, which can cause symptoms like debilitating fatigue, dizziness, shortness of breath, jaundice and in severe cases, chest pain or loss of consciousness.⁹

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.^{9,10} This condition affects both women and men and can affect people at any age with incidence increasing over the age of 50.^{10,11}

There are no Food and Drug Administration (FDA)-approved drugs indicated for wAIHA, and treatment typically consists of corticosteroids, broad immunosuppressants and B-cell directed therapies.⁹ With an unmet need for treatment in wAIHA, continued research for evidence-based potential therapies is critical.¹²

About fetal and neonatal alloimmune thrombocytopenia

Fetal and neonatal alloimmune thrombocytopenia (FNAIT) is a rare and potentially life-threatening alloimmune condition in which a pregnant person's immune system develops alloantibodies against fetal or newborn platelet antigens, leading to thrombocytopenia (low platelet counts) in the fetus or newborn.¹³

FNAIT can result in severe bleeding complications for a fetus or newborn and is characterized by organ bleeding in the gastrointestinal tract, lungs, or eyes.¹³ If a severe bleed occurs in the brain, termed intracranial hemorrhage (ICH), death or life-long neurologic effects may occur.¹³ ICH occurs in up to 26 percent of untreated pregnancies with FNAIT.¹⁴

It has an estimated incidence rate of 1 in 1000 pregnancies.^{13,15} There are no approved therapies for the treatment of FNAIT. Because FNAIT is not routinely screened for during pregnancy, the diagnosis of an affected FNAIT pregnancy often occurs postnatally.¹³

About DARZALEX[®] and DARZALEX FASPRO[®]

DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj) **received** U.S. FDA approval in May 2020 and is approved for nine indications in multiple myeloma, four of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.¹⁶ It is the only subcutaneous CD38-directed antibody approved to treat patients with MM. DARZALEX FASPRO[®] is co-formulated with recombinant human hyaluronidase PH20, Halozyme's ENHANZE[®] drug delivery technology.

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.¹⁷

DARZALEX[®] is the first CD38-directed antibody approved to treat multiple myeloma.¹⁷ DARZALEX[®]-based regimens have been used in the treatment of more than 585,000 patients worldwide and more than 239,000 patients in the

U.S. alone.

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

Since 2020, the National Comprehensive Cancer Network[®] (NCCN[®]) has recommended daratumumab-based combination regimens for the treatment of newly diagnosed multiple myeloma and relapsed and refractory multiple myeloma.[†] For newly diagnosed multiple myeloma in non-transplant candidates, the NCCN[®] guidelines recommend daratumumab in combination with lenalidomide and dexamethasone as a Category 1 preferred regimen; daratumumab in combination with bortezomib, melphalan, and prednisone as another recommended Category 1 regimen; and daratumumab in combination with bortezomib, cyclophosphamide, and prednisone as another recommended Category 2A regimen. For newly diagnosed multiple myeloma in transplant candidates, the NCCN[®] guidelines recommend daratumumab in combination with bortezomib, lenalidomide and dexamethasone as another recommended Category 2A regimen; daratumumab in combination with bortezomib, thalidomide and dexamethasone as a Category 2A regimen useful in certain circumstances; daratumumab in combination with carfilzomib, lenalidomide and dexamethasone as a Category 2A regimen useful in certain circumstances; and daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone as a Category 2A regimen useful in certain circumstances. For maintenance in transplant candidates, the NCCN[®] guidelines recommend daratumumab in combination with lenalidomide as useful in certain circumstances. In relapsed/refractory myeloma, four daratumumab regimens are listed as Category 1 preferred regimens for early relapses (1-3 prior therapies): daratumumab in combination with lenalidomide and dexamethasone; daratumumab in combination with bortezomib and dexamethasone; daratumumab in combination with carfilzomib and dexamethasone; and daratumumab in combination with pomalidomide and dexamethasone [after one prior therapy including lenalidomide and a proteasome inhibitor]. The NCCN[®] also recommends daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone as another Category 2A regimen for early relapses (1-3 prior therapies) and as monotherapy as a Category 2A regimen useful in certain circumstances for early relapse patients after at least three prior therapies, including a proteasome inhibitor and an immunomodulatory agent, or for patients who are double refractory to a PI and an immunomodulatory agent.

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

About CARVYKTI[®]

CARVYKTI[®] is a BCMA-directed, genetically modified autologous T-cell immunotherapy that 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 BCMAexpressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.

CARVYKTI[®] (cilta-cel) received U.S. Food and Drug Administration <u>approval</u> 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 <u>approved</u> 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) <u>approved</u> 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 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 <u>www.CARVYKTI.com</u>.

About TECVAYLI[®]

TECVAYLI[®] (teclistamab-cqyv) <u>received</u> approval from the U.S. FDA in October 2022 as an off-the-shelf (or ready-touse) antibody that is administered as a subcutaneous treatment for 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.¹⁸ The EC granted TECVAYLI[®] <u>conditional marketing</u> <u>authorization</u> (CMA) 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 <u>granted</u> <u>the approval</u> of a Type II variation application for TECVAYLI[®], providing the option for a reduced dosing frequency of 1.5 mg/kg every two weeks in patients who have achieved a complete response or better for a minimum of six months. TECVAYLI[®] 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. In February 2024, the U.S. FDA <u>approved</u> the supplemental Biologics License Application for TECVAYLI[®] for a reduced dosing frequency of 1.5 mg/kg every two weeks in patients with relapsed or refractory multiple myeloma who have achieved and maintained a CR or better for a minimum of six months.

For more information, visit www.TECVAYLI.com.

About TALVEY[®]

TALVEY[®] (talquetamab-tgvs) **received** approval from the U.S. FDA in August 2023 as a first-in-class GPRC5Dtargeting 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.¹⁹ Since FDA approval, 1,800 patients were treated with TALVEY[®]. 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 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.²⁰

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 non-malignant plasma cells, as well as some healthy tissues such as epithelial cells of the skin and tongue.

About IMBRUVICA[®]

IMBRUVICA[®] (ibrutinib) is a once-daily oral medication that is jointly developed and commercialized by Janssen Biotech, Inc., and Pharmacyclics LLC, an AbbVie company. IMBRUVICA[®] blocks the BTK protein, which is needed by normal and abnormal B cells, including specific cancer cells, to multiply and spread. By blocking BTK, IMBRUVICA[®] may help move abnormal B cells out of their nourishing environments and inhibit their proliferation.^{21,22, 23}

IMBRUVICA[®] is approved in more than 100 countries and has been used to treat more than 300,000 patients worldwide over the last decade. There are more than 50 company-sponsored clinical trials, including 18 Phase 3 studies, spanning more than 11 years evaluating the efficacy and safety of IMBRUVICA[®].

IMBRUVICA[®] was first approved by the U.S. FDA in November 2013, and today is indicated for adult patients in four disease areas. These include indications to treat adults with chronic lymphocytic leukemia/small lymphocytic lymphoma with or without 17p deletion; adults with Waldenström's macroglobulinemia; and adult and pediatric patients aged one year and older with previously treated chronic graft versus host disease after failure of one or more lines of systemic therapy.²⁴

About Nipocalimab

Nipocalimab is an investigational monoclonal antibody, designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies potentially without impact on other immune functions. This includes autoantibodies and alloantibodies that underlie multiple conditions across three key segments in the autoantibody space including Rare Autoantibody diseases, Maternal Fetal diseases mediated by maternal alloantibodies and Prevalent Rheumatology.^{25,26,27,28,29,30,31,32,33} Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.^{34,35}

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

- U.S. FDA Fast Track designation in hemolytic disease of the fetus and newborn (HDFN) and wAIHA in July 2019, gMG in December 2021 and FNAIT in March 2024
- 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 Sjögren's disease (SjD) in November 2024
- EU EMA Orphan medicinal product designation for HDFN in October 2019

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 https://www.innovativemedicine.jnj.com.

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Janssen Research & Development, LLC, Janssen Biotech, Inc., and Janssen Global Services, LLC are Johnson & Johnson companies.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of DARZALEX[®] (daratumumab), DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj), TALVEY[®] (talquetamab-tgvs),

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TECVAYLI[®] (teclistamab-cqyv), CARVYKTI[®] (ciltacabtagene autoleucel), IMBRUVICA[®] (ibrutinib) and nipocalimab. 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 Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

†See the NCCN Guidelines for detailed recommendations, including other treatment options.

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¹⁷ DARZALEX[®] U.S. Prescribing Information
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