News Release

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Janssen to Present the Strength and Promise of its Hematologic Malignancies Portfolio and Pipeline at ASH 2021

More than 80 abstracts will be presented, including data supporting Cilta-Cel, Teclistamab, Talquetamab, DARZALEX® (daratumumab) and IMBRUVICA® (ibrutinib)

Additional data for XARELTO® (rivaroxaban), Nipocalimab and DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) to highlight Janssen's research in other hematologic diseases

RARITAN, N.J., November 4, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that more than 45 company-sponsored abstracts, including 11 oral presentations, plus more than 35 investigator-initiated studies will be featured at the American Society of Hematology (ASH) Annual Meeting and Exposition. ASH is taking place at the Georgia World Congress Center in Atlanta and virtually from December 11-14, 2021.

"We are committed to advancing the science and treatment of hematologic malignancies and look forward to presenting the latest research from our

robust portfolio and pipeline during ASH 2021," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We continue to deepen and accelerate our understanding of blood cancers as we strive toward our vision – the elimination of cancer."

"As evidenced by our presence at ASH, we are continuously pushing boundaries to treat cancer," said Serge Messerlian, U.S. President, Oncology, Janssen Biotech, Inc. "At ASH, we look forward to working with the oncology community to advance the understanding and use of novel treatments and address unmet patient needs, with the ultimate goal of developing curative therapies. Our commitment to the blood cancer community is driven and inspired by our mission to reimagine care so patients can redefine living."

Transforming treatment paradigms for patients with multiple myeloma

Through years of research and community engagement, Janssen continues to build upon its knowledge of multiple myeloma and the challenges faced by patients at all stages of this complex disease. During ASH 2021, Janssen will present data that represents its multipronged approach to treating multiple myeloma in both the frontline and relapsed or refractory settings through the development of cell and biologic therapies.

Featured data on CAR-T and Bispecific therapies

Updated, longer-term results from the pivotal Phase 1b/2 CARTITUDE-1 study evaluating the B-cell maturation antigen (BCMA)-targeted chimeric antigen receptor T-cell (CAR-T) therapy ciltacabtagene autoleucel (cilta-cel) in heavily pre-treated patients who have relapsed and/or become refractory will be featured in an oral presentation (Abstract #549). Another oral presentation will report comparisons of patient outcomes with cilta-cel in the CARTITUDE-1 study with standard-of-care therapies from real-world clinical practice (Abstract #550).

Other data from the CARTITUDE program at ASH 2021 will provide data on the earlier use of cilta-cel, with updated results from Cohort A of the Phase 2 CARTITUDE-2 study, which included patients who were refractory to lenalidomide with progressive multiple myeloma after 1-3 lines of therapy (Abstract #3866) and the first data from Cohort B of the Phase 2 CARTITUDE-2 study which enrolled patients following early relapse after initial therapy that included proteasome inhibitors and immunomodulatory drugs (Abstract #2910). Both sets of results will be featured in poster presentations.

Separately, data being presented as a poster presentation will highlight the potential use of anakinra as a treatment for cytokine release syndrome associated with CAR-T therapy treatment (Abstract #2812).

Janssen will present the results from the Phase 1 and 2 MajesTEC-1 (Abstract #896) studies evaluating teclistamab (BCMAxCD3), an investigational, off-the-shelf, T-cell redirecting bispecific antibody in heavily pre-treated patients with multiple myeloma.

Updated results from the Phase 1 MonumenTAL-1 (Abstract #158) study, evaluating talquetamab (GPRC5DxCD3) – an investigational, off-the-shelf, T-cell redirecting bispecific antibody and the first directed at this novel target for heavily pre-treated patients with multiple myeloma – will be featured in an oral presentation. In addition, results from the TRiMM-2 study of talquetamab (Abstract #161) and teclistamab (Abstract #1647) in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) will also be presented.

DARZALEX® and DARZALEX FASPRO® featured data

Janssen continues to explore treatment combinations in newly diagnosed multiple myeloma. An oral presentation of updated results from the randomized Phase 2 GRIFFIN trial (Abstract #79) will present updated

response rates, including minimal residual disease (MRD), as well as progression-free survival (PFS), with DARZALEX® as part of an investigational quadruplet therapy regimen; a second oral presentation (Abstract #118) will examine the impact that clinical sequencing scenarios with DARZALEX®-based combinations in frontline versus second-line. In the maintenance setting, an oral presentation (Abstract #82) will share updated MRD results from the two-part Phase 3 CASSIOPEIA study of DARZALEX® in combination with bortezomib, thalidomide and dexamethasone (VTd) and autologous stem cell transplant (ASCT) followed by DARZALEX® maintenance therapy.

In real-world evidence, a poster presentation (Abstract #1965) examining potential healthcare disparities will highlight patient characteristics, treatment patterns and outcomes for Black and White patients with multiple myeloma who initiated treatment with DARZALEX®.

Janssen also continues to evolve the treatment approaches for rare hematologic diseases including newly diagnosed light chain (AL) amyloidosis. An oral presentation will feature updated data from the Phase 3 ANDROMEDA study (Abstract #159), which supported the accelerated approval of DARZALEX *FASPRO*® in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) as the first U.S. FDA-approved treatment for this rare and serious blood cell disorder.

Exploring new regimens in CLL/SLL treatment to address unmet patient needs

Through a comprehensive development program, Janssen continues to research additional IMBRUVICA®-based regimens to meet the range of needs of patients with chronic lymphocytic leukemia (CLL), including options that have the potential to provide treatment-free remissions.

At ASH 2021, new data for the investigational use of IMBRUVICA® in combination with venetoclax as an all-oral, fixed-duration therapy for the

treatment of frontline CLL/small lymphocytic lymphoma (SLL) will be presented. Oral presentations of this combination will feature MRD outcomes from the Phase 3 GLOW study (Abstract #70). It will also feature long-term data regarding disease-free survival from the Phase 2 CAPTIVATE study MRD cohort (Abstract #68), evaluating IMBRUVICA® plus venetoclax as a time-limited first-line treatment for patients with CLL/SLL that include a broad range of age and fitness groups.

Poster presentations of real-world data will reinforce the efficacy of IMBRUVICA® in patients with CLL/SLL treated in routine practice (Abstract #4112).

Advancing and delivering new insights around antithrombotic care

Blood clots, or venous thromboembolism (VTE), represent the second leading cause of death in people with cancer.[1] Janssen is committed to delivering new data to further validate and inform the use of XARELTO® (rivaroxaban) in patients at risk for cancer-associated thrombosis, helping evolve the standard of care for patients at risk for VTE. During ASH, Janssen will present data from CALLISTO, a comprehensive program of research on cancer-associated thrombosis (CAT), which included three randomized trials of XARELTO® versus low molecular weight heparin (LMWH) for the treatment of venous thrombosis in patients with solid and hematological cancers (SELECT-D, CASTA-DIVA and CONKO-11). The results of this pooled analysis (Abstract #1068) suggest XARELTO® may be an alternative treatment option for the prevention of VTE recurrence in cancer patients with VTE.

Janssen will also present data that further advances understanding and provides new insights in the antithrombotic space, including OSCAR-US, evaluating patient characteristics and temporal changes in anticoagulation treatment patterns in patients diagnosed with cancer-associated thrombosis (Abstract #2132) and RIVA-DM, an analysis of thromboembolism, bleeding, and vascular death among older and younger nonvalvular atrial fibrillation

patients with type 2 diabetes receiving XARELTO® or warfarin (Abstract #3234).

Advancing science for patients with wAIHA

Janssen continues to advance clinical trials exploring nipocalimab, an FcRn antagonist, in warm Autoimmune Hemolytic Anemia (wAIHA), an autoimmune disease characterized by the premature destruction of healthy red blood cells. A Trial in Progress (TiP) poster presentation of the ENERGY study (Abstract #1999) will highlight the rationale and study design for an adaptive, Phase 2/3 multicenter, randomized, double-blind, placebo-controlled study in patients with wAIHA whose aim is to evaluate the efficacy, safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of nipocalimab compared with placebo.

In real-world evidence, a poster presentation (Abstract #2000) will highlight the use of predictive analytics of a known clinically profiled patient cohort to support the identification of patients with wAIHA.

The above two abstracts were previously accepted and presented at the European Hematology Association (EHA) 2021 Annual Congress.

A complete list of Janssen-sponsored abstracts is available at Janssen.com/ASH2021.

About Cilta-cel

Cilta-cel is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates 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 cilta-cel CAR protein features two BCMA-targeting single domain antibodies 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.

In December 2017, Janssen Biotech, Inc. entered into an exclusive worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialize cilta-cel.

In addition to U.S. Breakthrough Therapy Designation (BTD) granted in December 2019, by the U.S. FDA, Janssen also received Orphan Drug Designation for cilta-cel, in February 2019. In December 2020, Janssen announced initiation of a rolling submission of its BLA to the U.S. FDA for cilta-cel, which was accepted under Priority Review in May 2021. In November 2021, Janssen announced the extension of the PDUFA date.

Cilta-cel received a PRIority MEdicines (PRIME) designation from the European Commission in April 2019, and the Orphan Drug Designation for cilta-cel from the European Commission in February 2020. A Breakthrough Therapy Designation for cilta-cel was granted in August 2020, for China. In April 2021, Janssen announced its submission of a Marketing Authorisation to the European Medicines Agency seeking approval of cilta-cel for the treatment of patients with relapsed and/or refractory multiple myeloma.

About Teclistamab

Teclistamab is an off-the-shelf, T-cell redirecting, bispecific antibody targeting both BCMA and CD3, a primary component of the T-cell receptor. CD3 is involved in activating T cells, and BCMA is expressed at high levels on multiple myeloma cells. Teclistamab redirects CD3-positive T cells to BCMA-expressing myeloma cells to induce killing of tumor cells. Results from Phase 1 studies demonstrated deep and durable response in heavily pretreated patients with multiple myeloma.[2]

Teclistamab is currently being evaluated in several studies both as monotherapy (NCT04557098) and is also being explored in combination studies (NCT04586426, NCT04108195, NCT04722146, NCT05083169). In 2020, the European Commission and the U.S. Food and Drug Administration each granted teclistamab Orphan Drug Designation for the treatment of multiple myeloma. In January 2021 and June 2021, teclistamab was granted PRIME designation by the European Commission and

BTD by the U.S. FDA, respectively. PRIME offers enhanced interaction and early dialogue to optimize drug development plans and speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.[3] The U.S. FDA grants Breakthrough Therapy Designation to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition and is based on preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.[4]

About Talquetamab

Talquetamab is a first-in-class, investigational T-cell redirecting bispecific antibody targeting both GPRC5D, a novel multiple myeloma target, and CD3, a primary component of the T-cell receptor and is involved in activating T cells, and GPRC5D is highly expressed on multiple myeloma cells. Results from the Phase 1 MonumenTAL-1 study demonstrated durable responses that deepen over time in heavily pre-treated patients with multiple myeloma.[5]

Talquetamab is currently being evaluated in a Phase 1/2 clinical study for the treatment of relapsed or refractory multiple myeloma (NCT03399799) and is also being explored in combination studies (NCT04586426). In January 2021, talquetamab was granted PRIME designation by the European Commission.

About DARZALEX *FASPRO*® and DARZALEX®

DARZALEX *FASPRO*® received U.S. FDA approval in May 2020 and is approved for six indications in multiple myeloma (MM), two of which are for frontline treatment in newly diagnosed patients who are transplant ineligible.[6] DARZALEX *FASPRO*® is the only subcutaneous CD38-directed antibody globally approved to treat patients with MM. DARZALEX *FASPRO*® is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. In January 2021, DARZALEX *FASPRO*® became the first FDA-approved therapy for light chain amyloidosis. In August 2012, Janssen Biotech, Inc. entered into an exclusive global license and development agreement with Genmab A/S to develop,

manufacture, and commercialize DARZALEX®.[7] DARZALEX® has been approved in eight indications, three of which are in the frontline setting, including for newly diagnosed patients who are transplant eligible as well as those who are ineligible.[8]

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
- As monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

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

- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant

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

For more information, visit www.DARZALEX.com.

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 Bruton's tyrosine kinase (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 in the lymph nodes, bone marrow, and other organs.[9,10,11]

IMBRUVICA® is approved in more than 100 countries and has been used to treat more than 250,000 patients worldwide. There are more than 50 company-sponsored clinical trials, including 18 Phase 3 studies, over 11 years evaluating the efficacy and safety of IMBRUVICA®.[12,13,14]

IMBRUVICA® was first approved by the U.S. Food and Drug Administration (FDA) in November 2013, and today is indicated for adult patients in six disease areas,

including five hematologic cancers. These include adults with CLL/small lymphocytic lymphoma (SLL) with or without 17p deletion (del17p) and adults with Waldenström's macroglobulinemia (WM), as well as adult patients with previously treated mantle cell lymphoma (MCL)*, adult patients with previously treated marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy* – and adult patients with previously treated chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.[14]

**Accelerated approval was granted for relapsed/refractory (R/R) MCL and R/R MZL based on overall response rate. Continued approval for R/R MCL and R/R MZL may be contingent upon verification and description of clinical benefit in confirmatory trials.*

Since 2019, the National Comprehensive Cancer Network® (NCCN®), recommends ibrutinib (IMBRUVICA®) as a preferred regimen for the initial treatment of CLL/SLL and has Category 1 treatment status for treatment-naïve patients without deletion 17p. In 2020, the NCCN Guidelines were updated to recommend IMBRUVICA®, with or without rituximab, as a preferred regimen for the treatment of R/R MCL, and as a Category 1 preferred regimen for both untreated and previously treated WM patients.

For more information, visit www.IMBRUVICA.com.

About Nipocalimab

Nipocalimab is a high affinity, fully human, aglycosylated, effectorless anti-FcRn IgG1 monoclonal antibody being studied for autoantibody-driven conditions including myasthenia gravis, hemolytic diseases of the fetus and newborn (HDFN), and warm autoimmune hemolytic anemia.[15] Nipocalimab targets FcRn, which plays a central role in prolonging the half–life of IgG autoantibodies.[16] Antagonism of this receptor reduces overall IgG autoantibody levels without widespread immune suppression. In 2019, nipocalimab received Fast Track Designation for wAIHA.[17]

In 2020, Johnson & Johnson acquired Momenta Pharmaceuticals, Inc., including full global rights to nipocalimab.

DARZALEX® and DARZALEX *FASPRO*® 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.

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, and pulmonary edema.

Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

When DARZALEX® dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of

DARZALEX® following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, ie, 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

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

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

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 832 patients with multiple myeloma (N=639) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*® as monotherapy or in combination, 9% of patients experienced a systemic administration-related reaction (Grade 2: 3.5%, Grade 3: 0.8%). Systemic administration-related reactions occurred in 8% of patients with the first injection, 0.4% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 9 minutes to 3.5 days). Of the 129 systemic administration-related reactions that occurred in 74 patients, 110 (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, and tachycardia. 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, and hypotension.

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.

Local Reactions

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.6%. The most frequent (>1%) injection-site reaction was injection-site erythema. These local reactions occurred a median of 5.5 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*®: 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%) 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, insomnia, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia. The most common hematologic laboratory

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

IMBRUVICA® IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hemorrhage: Fatal bleeding events have occurred in patients who received IMBRUVICA®. Major hemorrhage (≥ Grade 3, serious, or any central nervous system events; e.g., intracranial hemorrhage [including subdural hematoma], gastrointestinal bleeding, hematuria, and post procedural hemorrhage) occurred in 4% of patients, with fatalities occurring in 0.4% of 2,838 patients who received IMBRUVICA® in 27 clinical trials. Bleeding events of any grade including bruising and petechiae occurred in 39%, and excluding bruising and petechiae occurred in 23% of patients who received IMBRUVICA®, respectively.

The mechanism for the bleeding events is not well understood.

Use of either anticoagulant or antiplatelet agents concomitantly with IMBRUVICA® increases the risk of major hemorrhage. Across clinical trials, 3.1% of 2,838 patients who received IMBRUVICA® without antiplatelet or anticoagulant therapy experienced major hemorrhage. The addition of antiplatelet therapy with or without anticoagulant therapy increased this percentage to 4.4%, and the addition of anticoagulant therapy with or without antiplatelet therapy increased this percentage to 6.1%. Consider the risks and benefits of anticoagulant or antiplatelet therapy when co-administered with IMBRUVICA®. Monitor for signs and symptoms of bleeding.

Consider the benefit-risk of withholding IMBRUVICA® for at least 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections: Fatal and non-fatal infections (including bacterial, viral, or fungal) have occurred with IMBRUVICA® therapy. Grade 3 or greater infections occurred in 21%

of 1,476 patients who received IMBRUVICA® in clinical trials. Cases of progressive multifocal leukoencephalopathy (PML) and *Pneumocystis jirovecii* pneumonia (PJP) have occurred in patients treated with IMBRUVICA®. Consider prophylaxis according to standard of care in patients who are at increased risk for opportunistic infections.

Monitor and evaluate patients for fever and infections and treat appropriately.

Cytopenias: In 645 patients with B-cell malignancies who received IMBRUVICA® as a single agent, Grade 3 or 4 neutropenia occurred in 23% of patients, Grade 3 or 4 thrombocytopenia in 8% and Grade 3 or 4 anemia in 3%, based on laboratory measurements.

Monitor complete blood counts monthly.

Cardiac Arrhythmias and Cardiac Failure: Fatal and serious cardiac arrhythmias and cardiac failure have occurred with IMBRUVICA®. Grade 3 or greater ventricular tachyarrhythmias occurred in 0.2% of patients, Grade 3 or greater atrial fibrillation and atrial flutter occurred in 4%, and Grade 3 or greater cardiac failure occurred in 1% of 1,476 patients who received IMBRUVICA® in clinical trials. These events have occurred particularly in patients with cardiac risk factors, hypertension, acute infections, and a previous history of cardiac arrhythmias.

At baseline and then periodically, monitor patients clinically for cardiac arrhythmias and cardiac failure. Obtain an ECG for patients who develop arrhythmic symptoms (e.g., palpitations, lightheadedness, syncope, chest pain) or new onset dyspnea. Manage cardiac arrhythmias and cardiac failure appropriately, and if it persists, consider the risks and benefits of IMBRUVICA® treatment and follow dose modification guidelines.

Hypertension: Hypertension occurred in 19% of 1,476 patients who received IMBRUVICA® in clinical trials. Grade 3 or greater hypertension occurred in 8% of patients. Based on data from 1,124 of these patients, the median time to onset was 5.9 months (range, 0.03 to 24 months).

Monitor blood pressure in patients treated with IMBRUVICA® and initiate or adjust anti-hypertensive medication throughout treatment with IMBRUVICA® as appropriate.

Second Primary Malignancies: Other malignancies (10%), including non-skin carcinomas (4%), occurred among the 1,476 patients who received IMBRUVICA® in clinical trials. The most frequent second primary malignancy was non-melanoma skin cancer (6%).

Tumor Lysis Syndrome: Tumor lysis syndrome has been infrequently reported with IMBRUVICA®. Assess the baseline risk (e.g., high tumor burden) and take appropriate precautions.

Monitor patients closely and treat as appropriate.

Embryo-Fetal Toxicity: Based on findings in animals, IMBRUVICA® can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMBRUVICA® and for 1 month after the last dose. Advise males with female partners of reproductive potential to use effective contraception during the same time period.

ADVERSE REACTIONS

B-cell malignancies: The most common adverse reactions (≥30%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were thrombocytopenia (54.5%)*, diarrhea (43.8%), fatigue (39.1%), musculoskeletal pain (38.8%), neutropenia (38.6%)*, rash (35.8%), anemia (35.0%)*, and bruising (32.0%).

The most common Grade ≥3 adverse reactions (≥5%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia (20.7%)*, thrombocytopenia (13.6%)*, pneumonia (8.2%), and hypertension (8.0%).

Approximately 9% (CLL/SLL), 14% (MCL), 14% (WM) and 10% (MZL) of patients had a dose reduction due to adverse reactions. Approximately 4-10% (CLL/SLL),

9% (MCL), and 7% (WM [5%] and MZL [13%]) of patients discontinued due to adverse reactions.

cGVHD: The most common adverse reactions (≥20%) in patients with cGVHD were fatigue (57%), bruising (40%), diarrhea (36%), thrombocytopenia (33%)*, muscle spasms (29%), stomatitis (29%), nausea (26%), hemorrhage (26%), anemia (24%)*, and pneumonia (21%).

The most common Grade 3 or higher adverse reactions (≥5%) reported in patients with cGVHD were pneumonia (14%), fatigue (12%), diarrhea (10%), neutropenia (10%)*, sepsis (10%), hypokalemia (7%), headache (5%), musculoskeletal pain (5%), and pyrexia (5%).

Twenty-four percent of patients receiving IMBRUVICA® in the cGVHD trial discontinued treatment due to adverse reactions. Adverse reactions leading to dose reduction occurred in 26% of patients.

*Treatment-emergent decreases (all grades) were based on laboratory measurements.

DRUG INTERACTIONS

CYP3A Inhibitors: Co-administration of IMBRUVICA® with strong or moderate CYP3A inhibitors may increase ibrutinib plasma concentrations. Dose modifications of IMBRUVICA® may be recommended when used concomitantly with posaconazole, voriconazole, and moderate CYP3A inhibitors. Avoid concomitant use of other strong CYP3A inhibitors. Interrupt IMBRUVICA® if strong inhibitors are used short-term (e.g., for ≤7 days). See dose modification guidelines in USPI sections 2.3 and 7.1.

CYP3A Inducers: Avoid coadministration with strong CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment (based on Child-Pugh criteria): Avoid use of IMBRUVICA® in patients with severe hepatic impairment. In patients with mild or moderate impairment, reduce recommended IMBRUVICA® dose and monitor more frequently for adverse reactions of IMBRUVICA®.

Please see full Prescribing Information.

INDICATIONS

IMBRUVICA® (ibrutinib) is a kinase inhibitor indicated for the treatment of adult patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy.
    - This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL).
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion.
- Waldenström's macroglobulinemia (WM).
- Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.
    - This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

XARELTO® IMPORTANT SAFETY INFORMATION

XARELTO® may cause serious side effects, including:

- **Increased risk of blood clots if you stop taking XARELTO®.** People with atrial fibrillation (an irregular heart beat) that is not caused by a heart valve problem (nonvalvular) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. XARELTO® lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking XARELTO®, you may have increased risk of forming a clot in your blood.

  Do not stop taking XARELTO® without talking to the doctor who prescribes it for you. Stopping XARELTO® increases your risk of having a stroke. If you have to stop taking XARELTO®, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

- **Increased risk of bleeding.** XARELTO® can cause bleeding which can be serious, and may lead to death. This is because XARELTO® is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with XARELTO® you are likely to bruise more easily, and it may take longer for bleeding to stop. You may be at higher risk of bleeding if you take XARELTO® and have certain other medical problems.

  You may have a higher risk of bleeding if you take XARELTO® and take other medicines that increase your risk of bleeding, including:

  - Aspirin or aspirin-containing products
  - Long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs)
  - Warfarin sodium (Coumadin®, Jantoven®)
  - Any medicine that contains heparin
  - Clopidogrel (Plavix®)
  - Selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
  - Other medicines to prevent or treat blood clots

  Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:

- Unexpected bleeding or bleeding that lasts a long time, such as:
  - Nosebleeds that happen often
  - Unusual bleeding from gums
  - Menstrual bleeding that is heavier than normal, or vaginal bleeding
- Bleeding that is severe or you cannot control
- Red, pink, or brown urine
- Bright red or black stools (looks like tar)
- Cough up blood or blood clots
- Vomit blood or your vomit looks like "coffee grounds"
- Headaches, feeling dizzy or weak
- Pain, swelling, or new drainage at wound sites

- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like XARELTO®, and have medicine injected into their spinal and epidural area, or have a spinal puncture, have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:
  - A thin tube called an epidural catheter is placed in your back to give you certain medicine
  - You take NSAIDs or a medicine to prevent blood from clotting
  - You have a history of difficult or repeated epidural or spinal punctures
  - You have a history of problems with your spine or have had surgery on your spine

  If you take XARELTO® and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots.

  Tell your doctor right away if you have:
  - back pain

- tingling
- numbness
- muscle weakness (especially in your legs and feet)
- or loss of control of the bowels or bladder (incontinence)

XARELTO® is not for use in people with artificial heart valves.

XARELTO® is not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing.

Do not take XARELTO® if you:

- Currently have certain types of abnormal bleeding. Talk to your doctor before taking XARELTO® if you currently have unusual bleeding.
- Are allergic to rivaroxaban or any of the ingredients of XARELTO®.

Before taking XARELTO®, tell your doctor about all your medical conditions, including if you:

- Have ever had bleeding problems
- Have liver or kidney problems
- Have antiphospholipid syndrome (APS)
- Are pregnant or plan to become pregnant. It is not known if XARELTO® will harm your unborn baby.
  - **Tell your doctor** right away if you become pregnant during treatment with XARELTO®. Taking XARELTO® while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
  - If you take XARELTO® during pregnancy, **tell your doctor** right away if you have any signs or symptoms of bleeding or blood loss. **See "What is the most important information I should know about XARELTO®?" for signs and symptoms of bleeding.**
- Are breastfeeding or plan to breastfeed. XARELTO® may pass into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with XARELTO®.

Tell all of your doctors and dentists that you are taking XARELTO®. They should talk to the doctor who prescribed XARELTO® for you before you have any surgery, medical or dental procedure.

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

Some of your other medicines may affect the way XARELTO® works, causing side effects. Certain medicines may increase your risk of bleeding. **See "What is the most important information I should know about XARELTO®?"**

HOW SHOULD I TAKE XARELTO®?

- Take XARELTO® exactly as prescribed by your doctor.
- **Do not change your dose or stop taking XARELTO® unless your doctor tells you to.** Your doctor may change your dose if needed.
- Your doctor will decide how long you should take XARELTO®.
- XARELTO® may need to be stopped for one or more days before any surgery or medical or dental procedure. Your doctor will tell you when to stop taking XARELTO® and when to start taking XARELTO® again after your surgery or procedure.
- If you need to stop taking XARELTO® for any reason, talk to the doctor who prescribed XARELTO® to you to find out when you should stop taking it. Do not stop taking XARELTO® without first talking to the doctor who prescribes it to you.
- If you have difficulty swallowing XARELTO® tablets whole, talk to your doctor about other ways to take XARELTO®.
- Do not run out of XARELTO®. Refill your prescription of XARELTO® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have XARELTO® available to avoid missing any doses.
- If you take too much XARELTO®, go to the nearest hospital emergency room or call your doctor right away.

If you take XARELTO® for:

- **Atrial Fibrillation that is not caused by a heart valve problem:**
  - Take XARELTO® **1 time a day with your evening meal**.
  - If you miss a dose of XARELTO®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- **Blood clots in the veins of your legs or lungs:**
  - Take XARELTO® **1 or 2 times a day** as prescribed by your doctor.
  - For the **10-mg dose**, XARELTO® **may be taken with or without food.**
  - For the **15-mg and 20-mg doses,** take XARELTO® **with food at the same time each day.**
  - If you miss a dose:
    - **If you take the 15-mg dose of XARELTO® 2 times a day (a total of 30 mg of XARELTO® in 1 day):** Take XARELTO® as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your regularly scheduled time.
    - **If you take XARELTO® 1 time a day:** Take XARELTO® as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- **Hip or knee replacement surgery:**
  - Take XARELTO® 1 time a day with or without food.
  - If you miss a dose of XARELTO®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- **Blood clots in people hospitalized for an acute illness:**
  - Take XARELTO® 1 time a day, with or without food, while you are in the hospital and after you are discharged as prescribed by your doctor.
  - If you miss a dose of XARELTO®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- **Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease:**
  - Take XARELTO® 2.5 mg 2 times a day with or without food.
  - If you miss a dose of XARELTO®, take your next dose at your regularly scheduled time.
  - Take aspirin 75 to 100 mg once daily as instructed by your doctor.

- **Reducing the risk of a sudden decrease in blood flow to the legs, major amputation, serious heart problems or stroke in people with peripheral artery disease, including those who have recently had a procedure to improve blood flow to the legs:**
  - Take XARELTO® 2.5 mg 2 times a day with or without food.
  - If you miss a dose of XARELTO®, take your next dose at your regularly scheduled time.
  - Take aspirin 75 to 100 mg once daily as instructed by your doctor.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?

XARELTO® may cause serious side effects:

- See **"What is the most important information I should know about XARELTO®?"**

The most common side effect of XARELTO® was bleeding.

Call your doctor for medical advice about side effects. **You may report side effects to FDA at 1-800-FDA-1088.** You may also report side effects to Janssen Pharmaceuticals, Inc., at 1-800-JANSSEN (1-800-526-7736).

Please read full Prescribing Information, including Boxed Warnings, and Medication Guide for XARELTO®.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of teclistamab, talquetamab, cilta-cel (BCMA CAR-T), DARZALEX® (daratumumab), DARZALEX *FASRO*® (daratumumab and hyaluronidase-fihj), IMBRUVICA® (ibrutinib), XARELTO® (rivaroxaban), 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., any of the other Janssen Pharmaceutical Companies 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 January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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 the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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