News Release

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Janssen Headlines American Society of Hematology Annual Meeting With More Than 35 Presentations Highlighting Deep, Diverse Oncology Pipeline and Portfolio

- *New cilta-cel (BCMA CAR-T) data from the Phase 1b/2 CARTITUDE-1 study in relapsed or refractory multiple myeloma*
- *New DARZALEX® (daratumumab) and DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) data across early lines of treatment in multiple myeloma and in amyloid light-chain (AL) amyloidosis*
- *New data for bispecific antibodies talquetamab and teclistamab in relapsed or refractory multiple myeloma*
- *New data investigating IMBRUVICA® (ibrutinib) as time-limited therapy in chronic lymphocytic leukemia (CLL) and long-term results in CLL, mantle cell lymphoma (MCL) and Waldenström's Macroglobulinemia (WM)*

RARITAN, N.J., November 5, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today more than 35 company-sponsored studies, including 10 oral presentations, will be featured at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition taking place virtually December 5-8, 2020.

In multiple myeloma, highlights include Phase 1b/2 results for the B-cell maturation antigen (BCMA)-targeted chimeric antigen receptor T-cell (CAR-T) therapy ciltacabtagene autoleucel

(cilta-cel); new and updated data for the anti-CD38 monoclonal antibody DARZALEX® (daratumumab) and the subcutaneous formulation DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj); and new and updated data for bispecific antibodies talquetamab (GPRC5DxCD3) and teclistamab (BCMAxCD3), respectively.

In B-cell malignancies, Janssen will present new data for the Bruton's tyrosine kinase (BTK) inhibitor IMBRUVICA® (ibrutinib) as time-limited therapy in previously untreated CLL, including in combination with venetoclax.

Presentations in other blood disorders will include DARZALEX *FASPRO*™ data in the rare disease, amyloid light chain (AL) amyloidosis, and reversal agent data for JNJ-3093, an investigational Factor XIa inhibitor in thrombosis. Techniques for using predictive modeling to identify the U.S. patient population with warm autoimmune hemolytic anemia (wAIHA) will also be presented. Nipocalimab, a high affinity, fully human, aglycosylated, effectorless immunoglobulin G (IgG1) anti-neonatal Fc receptor (FcRn) monoclonal antibody, is currently being studied in a Phase 2/3 study in wAIHA. Further details about these data, products and the science that Janssen is advancing for patients with hematologic malignancies and blood disorders will be made available throughout the ASH Annual Meeting via the Janssen Oncology Virtual Newsroom.

"Janssen continues to progress a robust portfolio and differentiated pipeline through a strategy that is predicated on a deep scientific understanding of hematologic malignancies," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We look forward to presenting the latest science and results from our portfolio and pipeline during ASH as we work towards our ultimate goal — the elimination of cancer."

"Our team is committed to delivering transformational therapies, and we have been especially focused and diligent during the COVID-19 pandemic to maintain continuity of care for patients," said Serge Messerlian, President, Oncology, Janssen Biotech, Inc. "From DARZALEX and IMBRUVICA to cilta-cel and next-generation bispecific therapies, we are determined to transform the lives of patients who face a blood cancer diagnosis."

Highlights of results from Janssen-sponsored studies to be presented at ASH include:

Results from the Phase 1b/2 CARTITUDE-1 Study Evaluating Cilta-Cel in Patients with Relapsed or Refractory Multiple Myeloma

- **Oral presentation:** Phase 1b/2 efficacy and safety results for the BCMA CAR-T therapy cilta-cel from the ongoing CARTITUDE-1 study (Abstract #177)

- **Posters:** Additional cilta-cel data will include detailed analyses of cytokine release syndrome and health-related quality-of-life outcomes

Study Results of DARZALEX® and DARZALEX FASPRO™-Based Combination Regimens for Patients with Multiple Myeloma and AL Amyloidosis

- **Oral presentation:** New data from the randomized GRIFFIN study following 12 months of maintenance therapy with DARZALEX® in combination with lenalidomide or lenalidomide alone after induction with either DARZALEX®, lenalidomide, bortezomib and dexamethasone (D-VRd) or VRd in newly diagnosed, transplant-eligible patients with multiple myeloma (NDMM) (Abstract #549)
- **Oral presentation:** Primary data from the Phase 3 APOLLO study of DARZALEX *FASPRO*™ in combination with pomalidomide and dexamethasone (D-Pd) in patients with multiple myeloma who have received one or more prior lines of therapy (Abstract #412)
- **Oral presentation:** Results from the Phase 3 ANDROMEDA study of DARZALEX *FASPRO*™ in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) in patients with AL amyloidosis (Abstract #552)

First Reported Data for the GPRC5DxCD3 Bispecific Antibody Talquetamab in Relapsed or Refractory Multiple Myeloma

- **Oral presentation:** Phase 1 safety and efficacy data supporting the recommended Phase 2 dose of talquetamab, an investigational bispecific antibody that targets both GPRC5D and CD3 on T-cells, in the first-in-human trial of this agent in heavily pretreated patients with relapsed or refractory multiple myeloma (Abstract #290)

New Subcutaneous Data for the BCMAxCD3 Bispecific Teclistamab in Relapsed or Refractory Multiple Myeloma

- **Oral presentation:** Following initial teclistamab data presented at the American Society of Clinical Oncology (ASCO) 2020 Annual Meeting from the first-in-human trial in heavily pretreated patients with relapsed or refractory multiple myeloma, an oral presentation will highlight the first results for the subcutaneous formulation and updated Phase 1 results that support the recommended Phase 2 dose for the intravenous formulation (Abstract #180). Teclistamab is an investigational bispecific antibody targeting both BCMA and CD3 on T-cells

New Data on IMBRUVICA® Time-limited Combination Therapy in the Frontline Treatment of CLL (CAPTIVATE) and Longer-term Evidence in CLL, MCL and WM

- **Oral presentation:** The primary endpoint of disease-free survival with time-limited IMBRUVICA® plus venetoclax as the first-line CLL treatment in the minimal residual

disease (MRD)-guided cohort of the CAPTIVATE study will be featured in the CLL Therapy Oral Session (Abstract #123)

- **Posters:** Two presentations of integrated analyses of four clinical trials will highlight the durability of responses at four years and longer in patients with high-risk CLL (Abstract #2220 and Abstract #2219)
- Other IMBRUVICA® presentations will include longer-term safety and efficacy follow-up data for IMBRUVICA® plus rituximab from the Phase 3 iNNOVATE study in WM, and for IMBRUVICA® plus venetoclax from the SYMPATICO trial in relapsed or refractory MCL (Abstract #336 and Abstract #2938)

A complete list of Janssen-sponsored abstracts is available here.

About Cilta-cel

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy that is being studied in a comprehensive clinical development program for the treatment of patients with relapsed or refractory multiple myeloma and in earlier lines of treatment. The design consists of a structurally differentiated CAR-T with two BCMA-targeting single domain antibodies. 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 granted in December 2019, cilta-cel received a PRIority MEdicines (PRiME) designation from the European Commission in April 2019, and a Breakthrough Therapy Designation in China in August 2020. In addition, Janssen received U.S. FDA Orphan Drug Designation for cilta-cel in February 2019, and from the European Commission in February 2020.

About DARZALEX *FASPRO™* and DARZALEX®

DARZALEX *FASPRO™* received U.S. FDA approval in May 2020, in five indications, two of which are in the frontline setting in newly diagnosed patients who are transplant ineligible. DARZALEX *FASPRO™* is the only subcutaneous CD38-directed antibody approved to treat patients with multiple myeloma globally.[1] DARZALEX *FASPRO™* is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. In August 2012, Janssen entered into an exclusive global license and development agreement with Genmab A/S to develop, manufacture, and commercialize DARZALEX®.[2] 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.[3,4,5,6,7,8]

For more information, visit www.DARZALEX.com.

About Talquetamab

Talquetamab is a first-in-class investigational bispecific antibody targeting both GPRC5D, a novel multiple myeloma target, and CD3, the T-cell receptor.[9] CD3 is involved in activating T-cells and GPRC5D is highly expressed in multiple myeloma cells.[10,11] Results from preclinical studies in mouse models demonstrate that talquetamab induces the T-cell-mediated killing of GPRC5D-expressing multiple myeloma cells through the recruitment and activation of CD3-positive T-cells and inhibits tumor formation and growth.[10]

Talquetamab is currently being evaluated in a Phase 1 clinical study for the treatment of relapsed or refractory multiple myeloma and is also being explored in combination studies. The development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.*

About Teclistamab

Teclistamab is an investigational bispecific antibody targeting both BCMA and CD3. BCMA, B-cell maturation antigen, is expressed at significantly higher levels on multiple myeloma cells.[12,13,14,15,16] Teclistamab redirects CD3-positive T-cells to BCMA-expressing myeloma cells to induce cytotoxicity of the targeted cells.[14,15] Results from preclinical studies demonstrate that teclistamab kills myeloma cell lines and bone marrow-derived myeloma cells from heavily pretreated patients.[1515]

Teclistamab is currently being evaluated in a Phase 2 clinical study for the treatment of relapsed or refractory multiple myeloma and is also being explored in combination studies. The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.* In October 2020, the European Commission granted Janssen an orphan designation for teclistamab.

About IMBRUVICA®

IMBRUVICA® is the first-in-class Bruton's tyrosine kinase (BTK) inhibitor that is orally administered only once-daily. IMBRUVICA® is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company. IMBRUVICA® is indicated for adults in five disease areas (CLL, small lymphocytic leukemia, MCL, WM, marginal zone lymphoma) and chronic graft-versus-host disease (cGVHD).[17]

For more information, visit www.IMBRUVICA.com.

About JNJ-3093

In 2018, Janssen entered into a worldwide collaboration with Bristol Myers Squibb on a program to develop and commercialize JNJ-3093 (BMS-986177), an oral small molecule Factor XIa Inhibitor, for the prevention and treatment of major thrombotic conditions.

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.[18] Nipocalimab targets FcRn, which plays a central role in prolonging the half–life of IgG autoantibodies.[19] Antagonism of this receptor reduces overall IgG autoantibody levels without widespread immune suppression. In 2019, nipocalimab received Rare Pediatric Disease Designation and Orphan Drug Designation for nipocalimab in hemolytic disease of the fetus and newborn (HDFN) and Fast Track Designation for wAIHA.[20]

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

DARZALEX *FASPRO*™ IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX *FASPRO*™ is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

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*™.

Systemic Reactions

In a pooled safety population of 490 patients who received DARZALEX *FASPRO*™ as monotherapy or in combination, 11% of patients experienced a systemic administration-related reaction (Grade 2: 3.9%, Grade 3: 1.4%). Systemic administration-related reactions occurred in 10% of patients with the first injection, 0.2% with the second injection, and cumulatively 0.8% with subsequent injections. The median time to onset was 3.7 hours (range: 9 minutes to 3.5 days). Of the 84 systemic administration-related reactions that occurred in 52 patients, 73 (87%) occurred on the day of DARZALEX *FASPRO*™ administration. Delayed systemic administration-related reactions have occurred in less than 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, pruritis, 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 7 minutes (range: 0 minutes to 4.7 days) after starting administration of DARZALEX *FASPRO*™. Monitor for local reactions and consider symptomatic management.

Neutropenia
Daratumumab may increase neutropenia 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 *FASPRO*™ until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO*™, higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia
Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX *FASPRO*™ until recovery of platelets.

Embryo-Fetal Toxicity
Based on the mechanism of action, DARZALEX *FASPRO*™ can cause fetal harm when

administered to a pregnant woman. 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 *FASPRO*™ and for 3 months after the last dose.

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

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 *FASPRO*™*.* Type and screen patients prior to starting DARZALEX *FASPRO*™.

Interference with Determination of Complete Response

Daratumumab is a human 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 DARZALEX *FASPRO*™-treated patients with IgG kappa myeloma protein.

ADVERSE REACTIONS

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, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia.

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

Please see full Prescribing Information at www.DARZALEX.com.

DARZALEX® IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. 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, 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.

Interference With Serological Testing

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

Neutropenia and Thrombocytopenia

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

Interference With Determination of Complete Response

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

Embryo-Fetal Toxicity

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

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

ADVERSE REACTIONS

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

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

IMBRUVICA® IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage: Fatal bleeding events have occurred in patients who received IMBRUVICA®. Majorhemorrhage (≥ 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, including bruising and petechiae, occurred in 39% of patients who received IMBRUVICA®.

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: Fatal and serious cardiac arrhythmias have occurred with IMBRUVICA®. Grade 3 or greater ventricular tachyarrhythmias occurred in 0.2% of patients and Grade 3 or greater atrial fibrillation and atrial flutter occurred in 4% 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.

Periodically monitor patients clinically for cardiac arrhythmias. Obtain an ECG for patients who develop arrhythmic symptoms (e.g., palpitations, lightheadedness, syncope, chest pain) or new onset dyspnea. Manage cardiac arrhythmias 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 baseline hepatic impairment. In patients with mild or moderate impairment, reduce recommended IMBRUVICA® dose and monitor more frequently for adverse reactions of IMBRUVICA®.

Please click here **for full Prescribing Information.**

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.

Learn more at www.janssen.com. Follow us at @JanssenUS and @JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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), IMBRUVICA® (ibrutinib), cilta-cel, teclistamab, talquetamab, JNJ-3093 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 or 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 December 29, 2019, 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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*DuoBody is a registered trademark of Genmab A/S.

[1] Janssen Research & Development, LLC. A Study to Evaluate Subcutaneous Daratumumab in Combination With Standard Multiple Myeloma Treatment Regimens. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited July 5, 2019]. Available at: https://clinicaltrials.gov/ct2/show/NCT03412565. Identifier: NCT03412565
[2] Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational Anti-Cancer Agent Daratumumab." Issued August 30, 2012.
[3] Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA: First Human Anti-CD38 Monoclonal Antibody Available for the Treatment of Multiple Myeloma." Issued November 16, 2015.
[4] Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA in Combination with Two Standard of Care Regimens for the Treatment of Patients with Multiple Myeloma Who Have Received At Least One Prior Therapy." Issued November 21, 2016.
[5] Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by the U.S. FDA in Combination with Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Who Have Received At Least Two Prior Therapies." Issued June 16, 2017.
[6] Janssen Biotech, Inc. "Janssen Announces DARZALEX® (daratumumab) U.S. FDA Approval for Newly Diagnosed Patients with Multiple Myeloma who are Transplant Ineligible." Issued May 7, 2018.
[7] Janssen Biotech, Inc. "Janssen Announces U.S. FDA Approval of DARZALEX® (daratumumab) in Combination with Lenalidomide and Dexamethasone for Newly Diagnosed Patients with Multiple Myeloma Who Are Transplant Ineligible." Issued June 27, 2019.
[8] Janssen Biotech, Inc. "Janssen Announces U.S. FDA Approval of DARZALEX® (daratumumab) Combination Regimen for Newly Diagnosed, Transplant-Eligible Patients with Multiple Myeloma." Issued September 26, 2019.
[9] Ajai Chari. A Phase 1, First-in-Human Study of Talquetamab, a G Protein-Coupled Receptor Family C Group 5 Member D (GPRC5D) x CD3 Bispecific Antibody, in Patients with Relapsed and/or Refractory Multiple Myeloma (RRMM).: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7408718/
[10] Labrijn AF et al. Proc Natl Acad Sci USA. 2013;110:5145.
[11] Cohen, Y., et al. Hematology. 2013 Nov; 18(6):348-51.

[12] Labrijn AF et al. Proc Natl Acad Sci USA. 2013;110:5145.
[13] Frerichs KA et al. Clin Cancer Res. 2020; doi: 10.1158/1078-0432.CCR-19-2299.
[14] Cancer Research Institute. "Adoptive Cell Therapy: TIL, TCR, CAR T, AND NK CELL THERAPIES." Available at: https://www.cancerresearch.org/immunotherapy/treatment-types/adoptive-cell-therapy
[15] Cho SF et al. Frontiers in Immunology. 2018; 9: 1821.
[16] Benonisson H et al. Molecular Cancer Therapeutics. 2019 (18) (2) 312-322.
[17] IMBRUVICA® U.S. Prescribing Information, April 2020.
[18] Momenta Pharmaceuticals, Inc. "Momenta Pharmaceuticals Reports Second Quarter 2020 Financial and Operating Results" Issued August 10, 2020
[19] Gable K., Guptill J. Frontiers in Immunology. 2019; 10: 3052
[20] Momenta Pharmaceuticals, Inc. "Momenta Pharmaceuticals Launches Phase 2/3 Trial of M281 for the Treatment of Warm Autoimmune Hemolytic Anemia and is Granted." Issued August 1, 2019