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Janssen Shows Commitment to Advancing the Science and Treatment of Blood Cancers and Related Conditions With More Than 80 ASH 2018 Data Presentations From Differentiated Oncology and Cardiovascular Portfolios

- ***IMBRUVICA®*** *– Additional data supporting IMBRUVICA in newly diagnosed CLL, including Phase 3 results of IMBRUVICA plus obinutuzumab, and up to 7-year follow-up monotherapy data*
- ***DARZALEX®*** *– Data supporting DARZALEX in newly diagnosed and relapsed/refractory multiple myeloma, including long-term follow-up from the Phase 3 ALCYONE frontline study and CASTOR/POLLUX studies*
- ***CAR-T*** *– Updated analysis from the Phase 1 investigator-initiated study of CAR-T therapy LCAR-B38M in relapsed/refractory multiple myeloma*
- ***XARELTO®*** *– New studies on treatment and costs of venous thromboembolism in patients with cancer and in those who are morbidly obese*

RARITAN, NJ, November 1, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today 46 company-sponsored and more than 37 investigator-led abstracts will be presented at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, CA on December 1-4. Highlights include eight company-sponsored oral presentations, including data for the Bruton's tyrosine kinase (BTK) inhibitor IMBRUVICA® (ibrutinib), anti-CD38 monoclonal antibody DARZALEX® (daratumumab), as well as updated results from the BCMA-targeted chimeric antigen receptor T cell (CAR-T) therapy LCAR-B38M in multiple myeloma. Data for the Factor Xa inhibitor XARELTO® (rivaroxaban) are also being presented.

"The data we are presenting at ASH 2018 represent our commitment to continued scientific innovation in the treatment of blood cancers as we work toward our goal of ultimately delivering cures," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We are pleased to present findings from across our robust oncology portfolio in hematologic malignancies with important new data for IMBRUVICA and DARZALEX, and updated data from the Phase 1 study of BCMA-directed CAR-T therapy LCAR-B38M in multiple myeloma, which we continue to progress together with Legend Biotech."

"We are also excited to present new data on the use of XARELTO in patients with cancer," said Paul Burton, M.D., Ph.D., F.A.C.C., Vice President, Medical Affairs, Internal Medicine, Janssen Scientific Affairs, LLC. "These data, combined with the depth of our oncology portfolio, uniquely position Janssen to address multiple patient needs, including treating the co-morbidities associated with cancer."

A listing of abstracts is provided in the table below. Highlights of the data at ASH include the following:

New IMBRUVICA data in chronic lymphocytic leukemia

Results from the Phase 3 iLLUMINATE (PCYC-1130) study exploring the combination of IMBRUVICA plus obinutuzumab versus chlorambucil plus obinutuzumab in patients with newly diagnosed chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) will be presented during an oral session. These data served as the basis for a recent supplemental New Drug Application submission to the U.S. Food and Drug Administration, which received Priority Review on October 16.

Data with up to 7 years of follow-up for IMBRUVICA monotherapy in CLL/SLL will be presented for the first time, representing the longest follow-up for IMBRUVICA to date.

Notably, the National Cancer Institute-sponsored Phase 3 ALLIANCE A041202 study will be presented in the Plenary session – the three-arm study compared IMBRUVICA as a single agent versus IMBRUVICA plus rituximab versus bendamustine plus rituximab in newly diagnosed older CLL patients (Abstract #6).

DARZALEX long-term results across treatment lines in multiple myeloma

An oral presentation will update results from the Phase 3 ALCYONE study of DARZALEX in combination with bortezomib, melphalan and prednisone in newly diagnosed patients with multiple myeloma who are transplant ineligible. Additional oral presentations will highlight

efficacy and updated safety data from the safety run-in cohort of the Phase 2 GRIFFIN study evaluating treatment with DARZALEX in combination with bortezomib, lenalidomide and dexamethasone in newly diagnosed patients with multiple myeloma who are eligible for transplant, and the primary endpoint analysis from the Phase 2 LYRA study in newly diagnosed and relapsed patients with multiple myeloma.

Follow-up data from the Phase 3 CASTOR and POLLUX studies will report on the long-term efficacy and safety results of treatment with DARZALEX combinations in relapsed/refractory multiple myeloma, including the endpoint of minimal residual disease negativity.

LCAR-B38M CAR-T in multiple myeloma

An oral presentation will highlight updated results from one of the four study centers comprising the Phase 1, open-label investigator-initiated study evaluating LCAR-B38M, a CAR-T therapy directed against BCMA.

Janssen is advancing JNJ-68284528 in a Phase 1b/2 study, which is based on LCAR-B38M from co-development partner, Legend Biotech USA Inc.

XARELTO for venous thromboembolism prevention

Several studies will be presented that evaluate patients with cancer-associated thrombosis. In addition, a first-of-its-kind study to evaluate the safety, efficacy and costs of a Factor Xa inhibitor in morbidly obese patients with venous thromboembolism will be presented.

Abstract No.	**Title**	**Date/Time**
IMBRUVICA (ibrutinib)*		
	Oral Presentations	
Abstract #149	Ibrutinib Treatment in Waldenström's Macroglobulinemia: Follow-up Efficacy and Safety from the iNNOVATE Study	Saturday, December 1 1:00 p.m. PST
Abstract #402	The iR^2 Regimen (Ibrutinib, Lenalidomide, and Rituximab) Is Active with a Manageable Safety Profile in Patients with Relapsed/Refractory Non–Germinal Center-like Diffuse Large B-Cell Lymphoma	Sunday, December 2 1:15 p.m. PST
Abstract #691	Ibrutinib + Obinutuzumab Versus Chlorambucil + Obinutuzumab as First-Line Treatment in Patients with Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (CLL/SLL): Results from Phase 3 iLLUMINATE	Monday, December 3 10:30 a.m. PST
Abstract #784	A Global, Randomized, Placebo-Controlled, Phase 3 Study of Ibrutinib plus Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (RCHOP) in Patients with	Monday, December 3 3:30 p.m. PST

	Previously Untreated Non-Germinal Center B-Cell-Like (GCB) Diffuse Large B-Cell Lymphoma (DLBCL)	
Poster Presentations		
Abstract #1604	Efficacy of Ibrutinib-Rituximab versus Real-World (RW) Treatments for Patients with Waldenström's Macroglobulinemia (WM): Adjusted Comparison of iNNOVATE and the Lyon-Sud RW Database	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #2306	Front-line Ibrutinib Treatment Is Associated with Longer Time to Next Treatment, Net Total Cost Reduction, and Lower Healthcare Resource Utilization Compared to Chemoimmunotherapy in Patients with Chronic Lymphocytic Leukemia	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #1872	Chronic Lymphocytic Leukemia (CLL) Treatment Patterns, Dosing and Sequencing in the Era of Novel Targeted Therapies: Interim Analysis Results From the informCLL™ Real-World Registry	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #3133	Up to 7 Years of Follow-up of Single-Agent Ibrutinib in the Phase 1b/II PCYC-1102 Trial of First Line and Relapsed/Refractory Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3114	Ibrutinib Improves T-cell Proliferative Ability and Effector Function in Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL) Patients	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3498	Kinetic Catalytic Inhibition and Cell-Based Analysis, Not Just Target Binding, Are Required to Assess Kinase Selectivity of Covalent Inhibitors: Comparable BTK vs TEC Selectivity Profile for Ibrutinib and Acalabrutinib	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #4427	Single-Agent Ibrutinib versus Real-World (RW) Treatments for Patients with Chronic Lymphocytic Leukemia (CLL) and del11q: Adjusted Comparison of RESONATE-2™ and RESONATE™ with RW Databases	Monday, December 3 6:00 – 8:00 p.m. PST
Abstract #4147	Identification of a Genetic Signature Enriching for Response to Ibrutinib in Relapsed/Refractory Follicular Lymphoma in the DAWN Phase 2 Trial	Monday, December 3 6:00 – 8:00 p.m. PST
Abstract #4425	Prognostic Testing and Treatment Approaches in Patients with Chronic Lymphocytic Leukemia (CLL): Clinical Experience from an Interim Analysis of the informCLL™ Real-World Registry	Monday, December 3 6:00 – 8:00 p.m. PST
Abstract #4727	Diagnostic concordance of pathological methods and reports of hematopathologists compared to local nonspecialized pathologists in the diagnosis of lymphoma in Mexico	Monday, December 3 6:00 – 8:00 p.m. PST

Abstract #4394	Risk Model for Overall Survival for Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia: Validated for Patients on Ibrutinib, Idelalisib, Venetoclax, or Chemoimmunotherapy	Monday, December 3 6:00 – 8:00 p.m. PST
DARZALEX (daratumumab)		
	Oral Presentations	
Abstract #151	Efficacy and Updated Safety Analysis of a Safety Run-in Cohort from GRIFFIN, a Phase 2 Randomized Study of Daratumumab (Dara), Bortezomib (V), Lenalidomide, and Dexamethasone (D; Dara-VRd) vs. VRd in Patients (Pts) with Newly Diagnosed (ND) Multiple Myeloma (MM) Eligible for High-Dose Therapy (HDT) and Autologous Stem Cell Transplantation (ASCT)	Saturday, December 1 12:00 – 1:30 p.m. PST
Abstract #152	LYRA: A Phase 2 Study of Daratumumab (Dara) plus Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Newly Diagnosed and Relapsed Patients (Pts) with Multiple Myeloma (MM)	Saturday, December 1 12:15 – 1:30 p.m. PST
Abstract #156	One-Year Update of a Phase 3 Randomized Study of Daratumumab Plus Bortezomib, Melphalan, and Prednisone (D-VMP) Versus Bortezomib, Melphalan, and Prednisone (VMP) in Patients (Pts) with Transplant-Ineligible Newly Diagnosed Multiple Myeloma (NDMM): ALCYONE	Saturday, December 1 1:15 – 1:45 p.m. PST
	Poster Presentations	
Abstract #1996	Three-Year Follow up of the Phase 3 POLLUX Study of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) Alone in Relapsed or Refractory Multiple Myeloma (RRMM)	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #2006	Pharmacokinetics (PK) of Subcutaneous Daratumumab in Patients with Relapsed or Refractory (RR) Multiple Myeloma (MM): Primary Clinical Pharmacology Analysis of the Open-label, Multicenter, Phase 1b Study (PAVO)	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #1970	Split First Dose Administration of Daratumumab for the Treatment of Patients with Multiple Myeloma (MM): Clinical Pharmacology and Population Pharmacokinetic (PK) Analyses	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #1994	Updated Results from the Phase 2 CENTAURUS Study of Daratumumab (DARA) Monotherapy in Patients with Intermediate-Risk or High-Risk Smoldering Multiple Myeloma (SMM)	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #1995	Subcutaneous Daratumumab in Patients with Relapsed or Refractory Multiple Myeloma: Part 2 Safety and Efficacy Update of the Open-label, Multicenter, Phase 1b Study (PAVO)	Saturday, December 1 6:15 – 8:15 p.m. PST

Abstract #1617	Daratumumab Monotherapy for Patients with Relapsed or Refractory (R/R) Natural Killer/T-cell Lymphoma (NKTCL), Nasal Type: An Open-label, Single-arm, Multicenter Phase 2 Study	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #3270	Efficacy and Safety of Daratumumab, Bortezomib, and Dexamethasone (D-Vd) Versus Bortezomib and Dexamethasone (Vd) in First Relapse Patients: Two-Year Update of CASTOR	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3272	Evaluation of Sustained Minimal Residual Disease (MRD) Negativity in Relapsed/Refractory Multiple Myeloma (RRMM) Patients (Pts) Treated with Daratumumab in Combination with Lenalidomide Plus Dexamethasone (D-Rd) or Bortezomib Plus Dexamethasone (D-Vd): Analysis of POLLUX and CASTOR	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3550	Comparative Efficacy and Safety of Daratumumab in Combination with Bortezomib, Melphalan, and Prednisone (D-VMP) in Alcyone Versus Bortezomib, Melphalan, and Prednisone (VMP) in Vista in Newly Diagnosed Multiple Myeloma (NDMM) Patients Using Propensity Score Matching (PSM)	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3553	Impact of Modified Dose Schedule of Bortezomib, Melphalan, and Prednisone (VMP) for Previously Untreated, Transplant-Ineligible Patients with Multiple Myeloma (MM): A Matching-Adjusted Indirect Comparison	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3273	The Relationship between Minimal Residual Disease and Patient Reported Outcomes in Relapsed/Refractory Multiple Myeloma	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3288	Efficacy of Daratumumab in Combination with Standard of Care Regimens in Lenalidomide-Exposed or -Refractory Patients with Relapsed/Refractory Multiple Myeloma (RRMM): Analysis of CASTOR, POLLUX, and MMY1001 Studies	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3551	A Matching-Adjusted Indirect Treatment Comparison of Daratumumab-Bortezomib-Melphalan-Prednisone Versus Lenalidomide-Dexamethasone Continuous, Lenalidomide-Dexamethasone 18 Months, and Melphalan-Prednisone-Thalidomide	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3291	Characterization of Frontline Treatment Patterns and Attrition Rates According to Subsequent Lines of Therapy in Non-Transplant Patients with Newly Diagnosed Multiple Myeloma	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3541	Indirect Comparison Using Individual Patient Level Data Comparing Efficacy and Safety of a Daratumumab Monotherapy Vs. EU Approved Comparator Therapies in Patients with Multiple Myeloma	Sunday, December 2 6:00 – 8:00 p.m. PST

Abstract #3586	Patient Preferences for Multiple Myeloma (MM) Treatment: Interim Analysis of a Discrete Choice Experiment	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #4846	Safety of Split First Dosing Vs Standard Dosing Administration of Daratumumab Among Multiple Myeloma Patients Treated in a US Community Oncology Setting: A Real-World Observational Study	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #4741	Treatment Regimens for Patients with Newly Diagnosed Multiple Myeloma Who are Ineligible for Stem Cell Transplantation: A Systematic Literature Review and Network Meta-Analysis	Monday, December 3 6:00 – 8:00 p.m. PST
Abstract #4738	Evaluation and Comparison of Characteristics and Outcomes Among Frontline Multiple Myeloma (FLMM) Patients with and Without Stem Cell Transplant Treatment	Monday, December 3 6:00 – 8:00 p.m. PST
Abstract #4862	Measuring Patient Reported Outcomes in Multiple Myeloma: Are Legacy Instruments Fit for Purpose	Monday, December 3 6:00 – 8:00 p.m. PST
LCAR-B38M**		
Oral Presentation		
Abstract #955	Updated Analysis of a Phase 1, Open-Label Study of LCAR-B38M, a Chimeric Antigen Receptor T Cell Therapy Directed Against B-Cell Maturation Antigen, in Patients with Relapsed/Refractory Multiple Myeloma	Monday, December 3 4:30 – 6:00 p.m. PST
Translational Research		
Poster Presentations		
Abstract #1674	JNJ-64457107, a CD40 Agonist, Induces Cell Death in BCL6^{hi}IRF4^{neg} GCB Subtype of DLBCL	Saturday, December 1 6:15 – 8:15 p.m. PST
Abstract #2750	Immunogenomic Exploration of the Acute Myeloid Leukemia Microenvironment Identifies Determinants of T-cell Fitness	Sunday, December 2 6:00 – 8:00 p.m. PST
Other		
Oral Presentations		
Abstract #463***	Imetelstat Treatment Leads to Durable Transfusion Independence (TI) in RBC Transfusion-Dependent (TD), Non-Del(5q) Lower Risk MDS Relapsed/Refractory to Erythropoiesis-Stimulating Agent (ESA) Who Are Lenalidomide (LEN) and HMA Naïve	Sunday, December 2 4:30 – 6:00 p.m. PST
Abstract #685***	Imetelstat Is Effective Treatment for Patients with Intermediate-2 or High-Risk Myelofibrosis Who Have Relapsed on or Are Refractory to Janus Kinase Inhibitor Therapy: Results of a Phase 2 Randomized Study of Two Dose Levels	Monday, December 3 10:30 a.m. – 12:00 p.m. PST
Poster Presentation		

Abstract #3590	Patient-Reported Outcomes Validation of the FACT-Leu in Acute Myeloid Leukemia: A Review of Baseline Characteristics in AML2002	Sunday, December 2 6:00 – 8:00 p.m. PST
XARELTO (rivaroxaban)		
Poster Presentations		
Abstract #2537	Comparative Effectiveness, Safety, and Costs of Rivaroxaban and Warfarin Treatment Among Morbidly Obese Patients with Venous Thromboembolism	Sunday, December 2 6:00 – 8:00 p.m. PST
Abstract #3798	The Rate of Venous Thromboembolism in Cancer Patients Varies By Khorana Risk Category	Monday, December 3 6:00 – 8:00 p.m. PST
Abstract #3799	Healthcare Costs in Patients with Cancer Increase with Increasing Risk of Venous Thromboembolism	Monday, December 3 6:00 – 8:00 p.m. PST

*Includes abstracts that were submitted by IMBRUVICA co-development partner, Pharmacyclics LLC.

**Abstract was submitted by LCAR-B38M co-development partner, Legend Biotech USA Inc. Janssen is advancing JNJ-68284528 in a Phase 1b/2 study, which is based on LCAR-B38M.

***Includes abstracts that were submitted by imetelstat developer, Geron.

About IMBRUVICA

IMBRUVICA (ibrutinib) is a first-in-class, once-daily oral medicine that works differently than chemotherapy as it blocks the Bruton's tyrosine kinase (BTK) protein. The BTK protein sends important signals that cause B cells to abnormally mature and multiply.[1] IMBRUVICA targets and blocks BTK, inhibiting the survival and spread of cancer cells.

IMBRUVICA was first approved by the U.S. Food and Drug Administration in 2013, and today is indicated in six disease areas, including five hematologic cancers – chronic lymphocytic leukemia (CLL) with or without 17p deletion (del17p), small lymphocytic lymphoma (SLL) with or without del17p, Waldenström's macroglobulinemia (WM), previously-treated mantle cell lymphoma (MCL)*, previously-treated marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy* – and previously-treated chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.[2] IMBRUVICA is the first and only FDA-approved medicine in WM, MZL* and cGVHD. IMBRUVICA has been granted four Breakthrough Therapy Designations by the FDA, and it was one of the first medicines to receive U.S. approval through the Breakthrough Therapy Designation. IMBRUVICA is approved in more than 90 countries, and, to date, has been used to treat more than 135,000 patients worldwide across approved indications.[3]

IMBRUVICA is a comprehensively studied molecule in the oncology industry. The robust clinical oncology development program includes more than 150 active clinical trials studying IMBRUVICA alone and in combination with other medicines in several blood cancers and other serious diseases. For more information, visit www.IMBRUVICA.com.

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

IMBRUVICA IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage: Fatal bleeding events have occurred in patients treated with IMBRUVICA®. Grade 3 or higher bleeding events (intracranial hemorrhage [including subdural hematoma], gastrointestinal bleeding, hematuria, and post-procedural hemorrhage) have occurred in 3% of patients, with fatalities occurring in 0.3% of 1,011 patients exposed to IMBRUVICA® in clinical trials. Bleeding events of any grade, including bruising and petechiae, occurred in 44% of patients treated with IMBRUVICA®.

The mechanism for the bleeding events is not well understood.

IMBRUVICA® may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies and patients should be monitored for signs 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 24% of 1,011 patients exposed to 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: Treatment-emergent Grade 3 or 4 cytopenias including neutropenia (23%), thrombocytopenia (8%), and anemia (3%) based on laboratory measurements occurred in patients with B-cell malignancies treated with single agent IMBRUVICA®.
Monitor complete blood counts monthly.

Cardiac Arrhythmias: Fatal and serious cardiac arrhythmias have occurred with IMBRUVICA® therapy. 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 1,011 patients exposed to 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 has occurred in 12% of 1,011 patients treated with IMBRUVICA® in clinical trials with a median time to onset of 5 months (range, 0.03 to 22 months). Monitor patients for new onset hypertension or hypertension that is not adequately controlled after starting IMBRUVICA®. Adjust existing anti-hypertensive medications and/or initiate anti-hypertensive treatment as appropriate.

Second Primary Malignancies: Other malignancies (9%) including non-skin carcinomas (2%) have occurred in 1,011 patients treated with 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® therapy. 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 women to avoid becoming pregnant while taking IMBRUVICA® and for 1 month after cessation of therapy. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. Advise men to avoid fathering a child during the same time period.

ADVERSE REACTIONS

B-cell malignancies: The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were thrombocytopenia (58%)*, neutropenia (58%)*, diarrhea (42%), anemia (39%)*, rash (31%), musculoskeletal pain (31%), bruising (31%), nausea (28%), fatigue (27%), hemorrhage (23%), and pyrexia (20%).

The most common Grade 3 or 4 adverse reactions (≥5%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia (36%)*, thrombocytopenia (15%)*, and pneumonia (10%).

Approximately 6% (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%)*, stomatitis (29%), muscle spasms (29%), nausea (26%), hemorrhage (26%), anemia (24%)*, and pneumonia (21%). The most common Grade 3 or 4 adverse reactions (≥5%) reported in patients with cGVHD were fatigue (12%), diarrhea (10%), neutropenia (10%)*, pneumonia (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 and adverse reactions.

DRUG INTERACTIONS

CYP3A Inhibitors: Dose adjustments may be recommended.
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 IMBRUVICA® dose.

Please click here for full IMBRUVICA Prescribing Information.

About DARZALEX® (daratumumab) Injection, for Intravenous Infusion

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed antibody approved anywhere in the world.[4] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[5] DARZALEX® is believed to induce tumor cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as well as through apoptosis, in which a series of molecular steps in a cell lead to its death.[4] Subsets of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by DARZALEX®.[4] DARZALEX® is being evaluated in a comprehensive clinical development program across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[6,7,8, 9,10,11,12,13] Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant hematologic diseases in which CD38 is expressed, such as smoldering myeloma, as well as in solid tumors.[14,15,16] DARZALEX® is the first and only CD38-directed antibody to receive regulatory approval to treat multiple myeloma.[4]

DARZALEX IMPORTANT SAFETY INFORMATION[4]

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 Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were grade 1-2. Infusion reactions can also occur with subsequent infusions. Nearly all reactions occurred during infusion or within 4 hours of completing an infusion. Prior to the introduction of post-infusion medication in clinical trials, infusion reactions occurred up to 48 hours after infusion. 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.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently

monitor patients during the entire infusion. Interrupt infusion for reactions of any severity and institute medical management as needed. Permanently discontinue 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 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 are 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 – DARZALEX® 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. DARZALEX® dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors.

Thrombocytopenia – DARZALEX® may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. DARZALEX® dose delay may be required to allow recovery of platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with transfusions.

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.

Adverse Reactions – The most frequently reported adverse reactions (incidence ≥20%) in clinical trials were: infusion reactions, neutropenia, thrombocytopenia, fatigue, nausea, diarrhea, constipation, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy and upper respiratory tract infection.

In patients who received DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP), the most frequently reported adverse reactions (incidence ≥20%) were: upper respiratory tract infection (48%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions (≥2% compared to the VMP arm) were pneumonia (11%), upper respiratory tract infection (5%), and pulmonary edema (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ≥20% were lymphopenia (58%), neutropenia (44%), and thrombocytopenia (38%).

In patients who received DARZALEX® in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: upper respiratory tract infection (65%), infusion reactions (48%), diarrhea (43%), fatigue (35%), cough (30%), muscle spasms (26%), nausea (24%), dyspnea (21%) and pyrexia (20%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions (≥2% compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ≥20% were neutropenia (53%) and lymphopenia (52%).

In patients who received DARZALEX® in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: peripheral sensory neuropathy (47%), infusion reactions (45%), upper respiratory tract infection (44%), diarrhea (32%), cough (27%), peripheral edema (22%), and dyspnea (21%). The overall incidence of serious adverse reactions was 42%. Serious adverse reactions (≥2% compared to Vd) were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ≥20% were lymphopenia (48%) and thrombocytopenia (47%).

In patients who received DARZALEX® in combination with pomalidomide and dexamethasone, the most frequent adverse reactions (>20%) were fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (43%), diarrhea (38%), constipation (33%), dyspnea (33%), nausea (30%), muscle spasms (26%), back pain (25%),

pyrexia (25%), insomnia (23%), arthralgia (22%), dizziness (21%), and vomiting (21%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions reported in ≥5% patients included pneumonia (7%). Treatment-emergent hematology Grade 3-4 laboratory abnormalities ≥20% were anemia (30%), neutropenia (82%), and lymphopenia (71%).

In patients who received DARZALEX® as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). The overall incidence of serious adverse reactions was 33%. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ≥20% were lymphopenia (40%) and neutropenia (20%).

DRUG INTERACTIONS

Effect of Other Drugs on Daratumumab: The coadministration of lenalidomide, pomalidomide or bortezomib with DARZALEX® did not affect the pharmacokinetics of daratumumab.

Effect of Daratumumab on Other Drugs: The coadministration of DARZALEX® with bortezomib or pomalidomide did not affect the pharmacokinetics of bortezomib or pomalidomide.

About CAR-T and BCMA

CAR-T cells are an innovative approach to eradicating cancer cells by harnessing the power of a patient's own immune system. BCMA is a protein that is highly expressed on myeloma cells. By targeting BCMA via a CAR-T approach, CAR-T therapies may have the potential to redefine the treatment paradigm for multiple myeloma and potentially advance towards cures for patients with the disease.

WHAT IS XARELTO®?

XARELTO® is a prescription medicine used to:

- reduce the risk of stroke and blood clots in people who have a medical condition called atrial fibrillation that is not caused by a heart valve problem. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to the formation of blood clots, which can travel to the brain, causing a stroke, or to other parts of the body
- treat blood clots in the veins of your legs (deep vein thrombosis or DVT) or lungs (pulmonary embolism or PE)

- reduce the risk of blood clots happening again in people who continue to be at risk for DVT or PE after receiving treatment for blood clots for at least 6 months
- help prevent a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery

XARELTO® is also used with low dose aspirin to:

- reduce the reduce the risk of serious heart problems, heart attack and stroke in patients with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral arterial disease (a condition where the blood flow to the legs is reduced)

It is not known if XARELTO® is safe and effective in children.

XARELTO IMPORTANT SAFETY INFORMATION

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT XARELTO®?

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 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 people with artificial heart valves.**

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
- 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. You and your doctor should decide if you will take XARELTO® or breastfeed.

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.
• 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 **15-mg and 20-mg doses,** XARELTO® **should be taken with food.**
- For the **10-mg dose**, XARELTO® **may be taken with or without food.**
- Take your XARELTO® doses 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.

Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease or peripheral arterial disease:

- Take XARELTO® 2 times a day with or without food.
- If you miss a dose of XARELTO®, take your next dose at your regularly scheduled time.
- If you have difficulty swallowing the XARELTO® tablet whole, talk to your doctor about other ways to take XARELTO®.
- Your doctor will decide how long you should take XARELTO®**.**

- XARELTO® may need to be stopped, if possible for one or more days before any surgery or medical/dental procedure. If you need to stop taking XARELTO® for any reason, talk to your doctor to find out when you should stop taking it. **Do not stop taking XARELTO® without first talking to the doctor who prescribed it to you.** Your doctor will tell you when to start taking XARELTO® again after your surgery or procedure.
- Do not run out of XARELTO®. Refill your prescription for XARELTO® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you 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.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?

• The most common side effect of XARELTO® was bleeding.

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

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 click here for full Prescribing Information, including Boxed Warnings, and Medication Guide.

Trademarks are those of their respective owners. Janssen and Bayer together are developing rivaroxaban. For more information about XARELTO®, visit www.xarelto.com.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at @JanssenUS. Janssen Research & Development, LLC and Janssen Scientific Affairs, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 product development and the potential benefits and treatment impact of DARZALEX, IMBRUVICA, XARELTO and LCAR-B38M. 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 Scientific Affairs, 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 31, 2017, 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. Neither 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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