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Janssen to Present Latest Research from Robust Blood Cancer and Cardiovascular Disease Portfolios at this Year's American Society of Hematology Annual Meeting

Breadth of Janssen's portfolio to be highlighted, including first-time and new data presentations on BCMA-targeted CAR-T therapy JNJ-4528, DARZALEX® (daratumumab), IMBRUVICA® (ibrutinib) and XARELTO® (rivaroxaban)

RARITAN, N.J., November 6, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today 46 company-sponsored and more than 30 investigator-led abstracts will be presented at the American Society of Hematology (ASH) Annual Meeting in Orlando, Florida, December 7-10. Highlights include 13 oral presentations with new data for the BCMA-targeted CAR-T therapy JNJ-68284528 (JNJ-4528) in multiple myeloma; the anti-CD38 monoclonal antibody DARZALEX® (daratumumab) in multiple myeloma; the Bruton's tyrosine kinase (BTK) inhibitor IMBRUVICA® (ibrutinib) in B cell malignancies; and the Factor Xa inhibitor XARELTO® (rivaroxaban) for the reduction in the risk of deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients at risk, including for patients with cancer.

"The ASH Annual Meeting serves as a forum to engage the hematology community in the progress we continue to make in our portfolio and pipeline, and strengthen connections that advance oncology science," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head,

Oncology, Janssen Research & Development, LLC. "We are in a unique position to build upon our deep understanding of blood cancers and accelerate novel therapies, including a BCMA-targeted CAR-T therapy, with the aim of continuing to deliver innovative treatments to patients as quickly as possible."

"The breadth of XARELTO® data this year showcases our continued commitment to the many patients who are impacted by blood clots, including pediatric patients, people with cancer and those with acute medical illnesses," said James List, M.D., Ph.D., Global Therapeutic Area Head, Cardiovascular & Metabolism, Janssen Research & Development, LLC.

Highlights of the data at ASH include:

First Results from CARTITUDE-1 Study of JNJ-4528 in Patients with Relapsed/Refractory Multiple Myeloma

An oral presentation (Abstract #577) will report the first findings from the Phase 1b/2 CARTITUDE-1 study of the investigational CAR-T product JNJ-4528 in patients with relapsed and/or refractory multiple myeloma. Oral presentations will also include a translational science study (Abstract #928) supporting the emerging biomarker profile following administration of JNJ-4528 in CARTITUDE-1, as well as a long-term analysis (Abstract #579) of the durability of response and overall safety of LCAR-B38M from the LEGEND-2 study in patients with relapsed and/or refractory multiple myeloma. JNJ-4528 identifies the investigational product being studied in the U.S. and Europe, and LCAR-B38M identifies the investigational product in China.

DARZALEX® Overall Survival Results in Frontline and Updated Data from Several Combination Studies

Data presentations on the ongoing development of DARZALEX® in the frontline treatment of multiple myeloma will include results from the pre-specified overall survival (OS) analysis of the Phase 3 ALCYONE study of DARZALEX® with bortezomib, melphalan and prednisone (D-VMP) in newly diagnosed patients with multiple myeloma who are transplant ineligible. Additional oral presentations will feature updated results (Abstract #691) of DARZALEX® with lenalidomide, bortezomib and dexamethasone (D-RVd) in frontline, transplant-eligible multiple myeloma from the Phase 2 GRIFFIN study, and new results (Abstract #692) from the CASSIOPET study, a sub-study evaluating prognostic value using Positron Emission Tomography-Computed Tomography (PET-CT) in the Phase 3 CASSIOPEIA study of DARZALEX® with bortezomib, thalidomide and dexamethasone (D-VTd).

A separate oral presentation (Abstract #863) will feature long-term efficacy and safety data from the Phase 2 LYRA study investigating DARZALEX® in combination with cyclophosphamide, bortezomib and dexamethasone (D-CyBorD) induction therapy in patients with newly diagnosed and relapsed multiple myeloma.

IMBRUVICA®-based Combination Therapy in First-Line Treatment of CLL and Long-Term Follow-up of Single-Agent IMBRUVICA® in CLL and Relapsed/Refractory MCL

Data from two studies of IMBRUVICA® combination regimens in the first-line treatment of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) will be featured in the CLL Therapy Oral Session. Updated efficacy and safety data (Abstract #35) from the Phase 2 CAPTIVATE study evaluating IMBRUVICA® in combination with venetoclax will be presented. There will also be a presentation on four-year follow-up data (Abstract #33) from the Phase 3 E1912 study evaluating IMBRUVICA® in combination with rituximab versus chemotherapy, which was conducted by the ECOG-ACRIN Cancer Research Group and sponsored by the National Cancer Institute, part of the National Institutes of Health. In addition, extended follow-up by line of therapy will be presented from several studies in CLL and relapsed or refractory mantle cell lymphoma (MCL). IMBRUVICA®, a BTK inhibitor, is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.

New XARELTO® Data Focuses on Treating and Preventing Venous Thromboembolism (VTE) Across Many Different Patient Groups

Nine new clinical and real-world studies evaluating XARELTO® for the treatment and prevention of VTE, or blood clots, will be presented, including important analyses from the Phase 3 EINSTEIN study in children with VTE, and the MAGELLAN and MARINER trials in hospitalized, acutely ill patients. Additionally, findings from the real-world COSIMO study, part of the larger CALLISTO research program, will showcase patient-reported outcomes and treatment preferences of people with cancer-associated thrombosis.

Company-sponsored abstracts to be presented at the meeting include:

Abstract No.	**Title**	**Date/Time**
JNJ-4528 / LCAR-B38M		
	Oral Presentations	
Abstract #577	Results from CARTITUDE-1: A Phase 1b/2 Study of JNJ-4528, a CAR-T Cell Therapy Directed Against BCMA, in Patients with Relapsed and/or Refractory Multiple Myeloma	Monday, December 9 7:00 a.m. ET
Abstract #579*	Long-Term Follow-Up of a Phase 1, First-in-Human Open-Label Study of LCAR-B38M, a	Monday, December 9 7:30 a.m. ET

	Structurally Differentiated CAR-T Cell Therapy Targeting BCMA, in Patients with Relapsed/Refractory Multiple Myeloma (LEGEND-2)	
Abstract #928	Translational Analysis from CARTITUDE-1, an Ongoing Phase 1b/2 Study of JNJ-4528 BCMA-targeted CAR-T Cell Therapy in Relapsed and/or Refractory Multiple Myeloma, Indication Preferential Expansion of CD8+ T Cell Central Memory Cell Subset	Monday, December 9 6:15 p.m. ET
	Poster Presentation	
Abstract #1858*	Updated Phase 1 Results of a First-in-Human Open-Label Study of LCAR-B38M, a Structurally Differentiated CAR-T Cell Therapy Targeting BCMA (LEGEND-2)	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
DARZALEX® (daratumumab)		
	Oral Presentations	
Abstract #691	Depth of Response to Daratumumab, Lenalidomide, Bortezomib, and Dexamethasone Improves Over Time in Patients (pts) with Transplant-eligible Newly Diagnosed Multiple Myeloma: GRIFFIN Study Update	Monday, December 9 10:30 a.m. ET
Abstract #692	Evaluation of the Prognostic Value of Positron Emission Tomography-Computed Tomography at Diagnosis and Follow-up in Transplant-eligible Newly Diagnosed Multiple Myeloma Patients Treated in the Phase 3 CASSIOPEIA Study: Results of the CASSIOPET Companion Study	Monday, December 9 10:45 a.m. ET
Abstract #859	Daratumumab Plus Bortezomib, Melphalan, and Prednisone Versus Bortezomib, Melphalan, and Prednisone in Patients with Transplant-ineligible Newly Diagnosed Multiple Myeloma: Overall Survival in ALCYONE	Monday, December 9 4:30 p.m. ET
Abstract #863	Daratumumab Maintenance Therapy Improves Depth of Response and Results in Durable Progression-free Survival Following DARA Plus Cyclophosphamide, Bortezomib, and Dexamethasone Induction Therapy in Multiple Myeloma: Update of the LYRA Study	Monday, December 9 5:30 p.m. ET
	Poster Presentations	
Abstract #1568	Daratumumab Monotherapy for Patients with Relapsed or Refractory Natural Killer/T-cell Lymphoma, Nasal Type: Updated Results from an Open-label, Single-arm, Multicenter Phase 2 Study (VOLANS)	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1829	Daratumumab Plus Lenalidomide Versus Lenalidomide Alone as Maintenance Treatment in Patients with Newly Diagnosed Multiple Myeloma after Frontline Autologous Stem Cell Transplant: Use of Minimal Residual Disease as a Novel Primary Endpoint in the Phase 3 AURIGA Study	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1830	Effectiveness of Daratumumab in Combination with Lenalidomide and Dexamethasone vs. Common Standard-of-Care Regimens in Patients	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET

	with Non-Transplant Newly Diagnosed Multiple Myeloma (PEGASUS)	
Abstract #1831	Randomized Phase 2 Study of Subcutaneous Daratumumab Plus Carfilzomib/Dexamethasone Versus Carfilzomib/Dexamethasone Alone in Patients with Multiple Myeloma who have been Previously Treated with Intravenous Daratumumab to Evaluate Retreatment (LYNX)	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1865	Randomized, Open-Label, Non-inferiority, Phase 3 Study of Subcutaneous Versus Intravenous Daratumumab Administration in Patients with Relapsed or Refractory Multiple Myeloma: COLUMBA Update	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1866	Four-Year Follow-up of the Phase 3 POLLUX Study of Daratumumab Plus Lenalidomide and Dexamethasone Versus Lenalidomide and Dexamethasone (Rd) Alone in Relapsed or Refractory Multiple Myeloma	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1875	Daratumumab Plus Lenalidomide and Dexamethasone Versus Lenalidomide and Dexamethasone in Patients with Newly Diagnosed Multiple Myeloma Ineligible for Transplant: Updated Analysis of MAIA	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1876	Final Analysis of a Phase 1b Study of Daratumumab in Combination with Carfilzomib and Dexamethasone for Relapsed or Refractory Multiple Myeloma (EQUULEUS)	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1906	Randomized, Open-Label, Non-inferiority, Phase 3 Study of Subcutaneous Versus Intravenous Daratumumab Administration in Patients with Relapsed or Refractory Multiple Myeloma: Body Weight Subgroup Analysis of COLUMBA	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #2142	An Adjusted Treatment Comparison of Bortezomib/Cyclophosphamide/Dexamethasone and Bortezomib/Thalidomide/Dexamethasone from Real-World Data in Patients with Newly Diagnosed Multiple Myeloma Who Are Transplant-Eligible	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #2143	Comparison of Daratumumab Plus Bortezomib, Melphalan, and Prednisone with Standard of Care for Patients from Latin America with Newly Diagnosed Multiple Myeloma Who Were Transplant Ineligible: A Propensity Score Matching Analysis	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #2144	A Network Meta-Analysis to Evaluate Comparative Effectiveness of Frontline Treatments for Patients with Newly Diagnosed Multiple Myeloma Who Are Transplant-Ineligible	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #3151	Daratumumab Subcutaneous Delivery in Relapsed or Refractory Multiple Myeloma: Population Pharmacokinetics and Exposure-response Analysis (COLUMBA)	Sunday, December 8 6:00 p.m. – 8:00 p.m. ET
Abstract #3152	Subcutaneous Daratumumab Plus Standard Treatment Regimens in Patients with Multiple Myeloma Across Lines of Therapy: PLEIADES Study Update	Sunday, December 8 6:00 p.m. – 8:00 p.m. ET

Abstract #3192	Efficacy and Safety of Daratumumab, Bortezomib, and Dexamethasone Versus Bortezomib and Dexamethasone in First Relapse Patients with Multiple Myeloma: Four-Year Update of CASTOR	Sunday, December 8 6:00 p.m. – 8:00 p.m. ET
Abstract #4715	Economic Burden of Emergency Room Visits and Hospitalizations among Newly Diagnosed Multiple Myeloma Patients in the United States	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Abstract #4737	Discrete Event Simulation Model to Evaluate the Impact of Treatment Sequences on Long-term Patient Outcomes in Multiple Myeloma	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Abstract #4739	Impact of Modified Thalidomide Dosing in Bortezomib/Thalidomide/Dexamethasone for Patients with Newly Diagnosed Multiple Myeloma Who Are Transplant-eligible: A Matching-adjusted Indirect Comparison	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Abstract #4740	Comparative Efficacy and Safety of Bortezomib, Thalidomide, and Dexamethasone (VTd) Without and With Daratumumab (D-VTd) from CASSIOPEIA Versus VTd from PETHEMA/GEM in Patients with Newly Diagnosed Multiple Myeloma Using Propensity Score Matching	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Abstract #4742	Expanded Meta-analyses Confirms the Association Between MRD and Long-term Survival Outcomes in Multiple Myeloma	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Smoldering Myeloma		
	Poster Presentation	
Abstract #4385***	High Dimensional Immune Profiling in Smoldering Multiple Myeloma Identifies Novel Organizing Features of the Tumor Microenvironment	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
IMBRUVICA® (ibrutinib)**		
	Oral Presentations	
Abstract #35	Ibrutinib Plus Venetoclax for First-line Treatment of CLL/SLL: Results from MRD Cohort of Phase 2 CAPTIVATE Study	Saturday, December 7 8:30 a.m. ET
Abstract #354	Clinical Impact of Ibrutinib with R-CHOP in Untreated Non-GCB DLBCL Co-Expressing BCL2 and MYC Genes in the Phase 3 PHOENIX Trial	Sunday, December 8 7:30 a.m. ET
Abstract #761	Phase 2 Results of the iR2 Regimen (Ibrutinib, Lenalidomide, and Rituximab) in Patients with Relapsed/Refractory Non-germinal Center B Cell–Like (Non-GCB) Diffuse Large B-Cell Lymphoma (DLBCL)	Monday, December 9 3:45 p.m. ET
	Poster Presentations	
Abstract #1538	Long-Term Outcomes with Ibrutinib Versus the Prior Regimen: A Pooled Analysis in Relapsed/Refractory MCL with up to 7.5 Years of Extended Follow-up	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #1755	Cirmtuzumab, a ROR1 Targeted mAb, Reverses Cancer Stemness, and its Combination with Ibrutinib are Safe, Effective and Causes Reversal of Cancer Stemness: Planned Analysis of the Phase 1/2 CIRLL Trial for CLL and MCL	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET

Abstract #3054	Using Ibrutinib in Earlier Lines of Treatment Results in Better Outcomes for Patients with CLL/SLL (RESONATE/RESONATE-2)	Sunday, December 8 6:00 p.m. – 8:00 p.m. ET
Cusatuzumab		
	Oral Presentation	
Abstract #234	Targeting CD70 with Cusatuzumab Eliminates Acute Myeloid Leukemia Stem Cells in Humans (ARGX1601)	Saturday, December 7 2:00 p.m. – 3:30 p.m. ET
	Poster Presentation	
Abstract #3918	The Combination of the BCL-2 Antagonist Venetoclax with the CD70-Targeting Antibody Cusatuzumab Synergistically Eliminates Primary Human Leukemia Stem Cells	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
XARELTO® (rivaroxaban)		
	Oral Presentations	
Abstract #163	Increased Risk of Death in Acutely Ill Medical Patients with Asymptomatic Proximal Deep Vein Thrombosis or Symptomatic Venous Thromboembolism: Insights from the MAGELLAN Study	Saturday, December 7 12:00 p.m. ET
Abstract #164	Rivaroxaban for Treatment of Pediatric Venous Thromboembolism. An EINSTEIN-JR Phase 3 Dose-Exposure-Response Evaluation	Saturday, December 7 12:15 p.m. ET
	Poster Presentations	
Abstract #1143	Cancer Associated Thrombosis is Related to Higher Mortality Across All Risk Levels for Venous Thromboembolism	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #2159	Patient Preferences Regarding Anticoagulation Therapy in Cancer Patients Having Experienced a VTE Event - a Discrete Choice Experiment in the COSIMO Study	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #2161	Baseline Characteristics and Clinical Outcomes from the Cancer Associated Thrombosis – Patient Reported Outcomes with Rivaroxaban (COSIMO) Trial	Saturday, December 7 5:30 p.m. – 7:30 p.m. ET
Abstract #2437	Rivaroxaban Reduces the Levels of Extracellular Vesicles in Patients with Venous Thromboembolism and Non-Valvular Atrial Fibrillation	Sunday, December 8 6:00 p.m. – 8:00 p.m. ET
Abstract #2441	Association of Bleeding Severity with Mortality with in-Hospital and Extended Thromboprophylaxis in the Medically Ill in the MAGELLAN Trial	Sunday, December 8 6:00 p.m. – 8:00 p.m. ET
Abstract #3669	Association of Bleeding Severity with Mortality with Extended Thromboprophylaxis in the Medically Ill in the MARINER Trial	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Abstract #3671	Rivaroxaban and Extended Thromboprophylaxis in Acutely Ill Medical Patients with History of Cancer: Insights from the MAGELLAN and MARINER Studies	Monday, December 9 6:00 p.m. – 8:00 p.m. ET
Other		
	Poster Presentation	
Abstract #4478	FREESIA Study Design: JNJ-53718678 in Hematopoietic Cell Transplant Recipients with	Monday, December 9 6:00 p.m. – 8:00 p.m. ET

	Respiratory Syncytial Virus Infection of the Upper Respiratory Tract	
Notable Investigator-Initiated Study		
Oral Presentation		
Abstract #33	Phase 3 E1912 (ECOG) study evaluating IMBRUVICA plus rituximab vs. fludarabine, cyclophosphamide and rituximab (FCR) for previously untreated CLL in patients aged 70 or younger	Saturday, December 7 8:00 a.m. ET

*Abstract was submitted by LCAR-B38M co-development partner, Legend Biotech USA Inc. Janssen is advancing clinical development of JNJ-4528, which is based on LCAR-B38M.
** Includes abstracts that were submitted by IMBRUVICA co-development partner, Pharmacyclics LLC.
*** Abstract was submitted by Janssen, the Multiple Myeloma Research Foundation and Mount Sinai Health System.

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. B-cell maturation antigen (BCMA) is a protein that is highly expressed on myeloma cells. By targeting BCMA via this approach, CAR-T therapies may have the potential to redefine the treatment paradigm for multiple myeloma.

About DARZALEX® (daratumumab)

DARZALEX® (daratumumab), the first CD38-directed antibody approved anywhere in the world, is the only CD38-directed antibody approved to treat multiple myeloma. CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease. DARZALEX® binds to CD38 and inhibits tumor cell growth causing myeloma cell death. DARZALEX® may also have an effect on normal cells. 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. 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.

In the U.S., DARZALEX® received initial FDA approval in November 2015 as a monotherapy for patients with multiple myeloma 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® received additional approvals in November 2016 in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. In June 2017, DARZALEX® received approval in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a PI. In May 2018, DARZALEX® received approval in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT, making it the first monoclonal

antibody approved for newly diagnosed patients with this disease. In June 2019, DARZALEX® received approval in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are transplant ineligible. In September 2019, DARZALEX® received approval in combination with bortezomib, thalidomide and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.

In August 2012, Janssen Biotech, Inc. entered into a global license and development agreement with Genmab A/S, which granted Janssen an exclusive license to develop, manufacture and commercialize DARZALEX®. For the full U.S. Prescribing Information, please visit www.DARZALEX.com.

About IMBRUVICA® (ibrutinib)

IMBRUVICA® (ibrutinib) is a 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 tell B cells to mature and produce antibodies. BTK signaling is needed by 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.

IMBRUVICA® is approved in more than 95 countries in at least one indication, and, to date, has been used to treat more than 170,000 patients worldwide across approved indications. It was first approved by the U.S. Food and Drug Administration (FDA) in November 2013, and today is indicated in six disease areas, including five hematologic cancers – chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) with or without 17p deletion (del17p), Waldenström's macroglobulinemia (WM), previously-treated patients with mantle cell lymphoma (MCL)*, previously-treated patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy* – and previously-treated patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

** 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.*

As of 2019, the National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 28 leading cancer centers devoted to patient care, research, and education, recommends ibrutinib (IMBRUVICA®) as the only treatment option for initial therapy of treatment-naïve patients with CLL/SLL without del(17p)/TP53 mutation with a Category 1 recommendation. IMBRUVICA® is the only FDA-approved medicine in WM 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 with the Breakthrough Therapy Designation.

IMBRUVICA® is a comprehensively studied molecule, with 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.

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
- help prevent blood clots in certain people hospitalized for an acute illness and after discharge, who are at risk of getting blood clots because of the loss of or decreased ability to move around (mobility) and other risks for getting blood clots, and who do not have a high risk of bleeding

XARELTO® is used with low dose aspirin to:

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

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

DARZALEX® IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX® (daratumumab) 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 DARZALEX®. 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 and Thrombocytopenia – DARZALEX® may increase neutropenia and/or thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to the 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 and/or platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors for neutropenia or transfusions for

thrombocytopenia.

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%) were: infusion reactions, neutropenia, thrombocytopenia, fatigue, asthenia, nausea, diarrhea, constipation, decreased appetite, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy, bronchitis, pneumonia, and upper respiratory tract infection.

DARZALEX® in combination with lenalidomide and dexamethasone (DRd): The most frequent (≥20%) adverse reactions for newly diagnosed or relapsed/refractory patients were, respectively, infusion reactions (41%, 48%), diarrhea (57%, 43%), nausea (32%, 24%), fatigue (40%, 35%), pyrexia (23%, 20%), upper respiratory tract infection (52%, 65%), muscle spasms (29%, 26%), dyspnea (32%, 21%), and cough (30%, 30%). In newly diagnosed patients, constipation (41%), peripheral edema (41%), back pain (34%), asthenia (32%), bronchitis (29%), pneumonia (26%), peripheral sensory neuropathy (24%), and decreased appetite (22%) were also reported. In newly diagnosed patients, serious adverse reactions (≥2% compared to Rd) were pneumonia (15%), bronchitis (4%), and dehydration (2%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (56%), lymphopenia (52%), and leukopenia (35%). In relapsed/refractory patients, serious adverse reactions (≥2% compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (53%) and lymphopenia (52%).

DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP): The most frequently reported adverse reactions (≥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%).

DARZALEX® in combination with bortezomib and dexamethasone (DVd): The most frequently

reported adverse reactions (≥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%).

DARZALEX® in combination with bortezomib, thalidomide, and dexamethasone (DVTd): The most frequent adverse reactions (≥20%) were infusion reactions (35%), nausea (30%), upper respiratory tract infection (27%), pyrexia (26%), and bronchitis (20%). Serious adverse reactions (≥2% compared to the VTd arm) were bronchitis (DVTd 2% vs VTd <1%) and pneumonia (DVTd 6% vs VTd 4%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (59%), neutropenia (33%), and leukopenia (24%).

DARZALEX® in combination with pomalidomide and dexamethasone (DPd): 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% of patients included pneumonia (7%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (82%), lymphopenia (71%), and anemia (30%).

DARZALEX® as monotherapy: The most frequently reported adverse reactions (≥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%).

Please click here to see the full Prescribing Information.

IMBRUVICA® IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage: Fatal bleeding events have occurred in patients treated with 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) have occurred in 4% of patients, with fatalities occurring in 0.4% of 2,838 patients exposed to IMBRUVICA® in 27 clinical trials. Bleeding events of any grade, including bruising and petechiae, occurred in 39% of patients treated with 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. In IMBRUVICA® clinical trials, 3.1% of patients taking 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 24% of 1,124 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 1,124 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 of any grade occurred in 12% of 1,124 patients treated with IMBRUVICA® in clinical trials. Grade 3 or greater hypertension occurred in 5% of patients with a median time to onset of 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%) have occurred in 1,124 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%)*, diarrhea (41%), anemia (38%)*, neutropenia (35%)*, musculoskeletal pain (32%), rash (32%), bruising (31%), nausea (26%), fatigue (26%), hemorrhage (24%), 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 (18%)*, thrombocytopenia (16%)*, and pneumonia (14%).

Approximately 7% (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 2.4 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 IMBRUVICA® dose.

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

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 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, who have a history of blood clots.

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 or peripheral artery 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.

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

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 product development and the potential benefits and

treatment impact of DARZALEX, IMBRUVICA, XARELTO and JNJ-4528. 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 The Janssen Pharmaceutical Companies of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory 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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