Media Inquiries:
Kellie McLaughlin
Phone: 1-908-927-7477
Mobile: 1-609-468-8356

Satu Kaarina Glawe
Mobile: +49 172 294 6264

Investor Relations:
Lesley Fishman
Phone: 1-732-524-3922

U.S. Medical Inquiries:
(ZYTIGA and DARZALEX):
1-800-526-7736

(IMBRUVICA –
Pharmacyclics/AbbVie):
1-877-877-3536

ASCO 2017: Janssen to Present 19 Abstracts in Prostate Cancer and a Spectrum of Blood Cancers; Includes Data on Abiraterone Acetate, Daratumumab and Ibrutinib

- Phase 3 pivotal trial results for abiraterone acetate selected to be featured in the ASCO Plenary Session and Press Program
- Follow-up data for daratumumab from the CASTOR/POLLUX pivotal trials in relapsed or refractory multiple myeloma, as well as early data for daratumumab combination therapy in frontline setting
- Four-year follow-up data on the long-term efficacy and safety of ibrutinib in previously treated chronic lymphocytic leukemia (CLL) patients, including those with high-risk disease

RARITAN, NJ, May 17, 2017 – New data for both approved and investigational oncology compounds from Janssen Research & Development, LLC will be presented at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting. In total, 19 company-sponsored abstracts have been accepted for presentation, including for abiraterone acetate, daratumumab and ibrutinib. Most notably, Phase 3 pivotal trial results for abiraterone acetate will be featured in the ASCO Press Briefing on Saturday, June 3rd and have been selected for inclusion in the Plenary Session on Sunday, June 4th.

“We are focused on delivering therapies that not only treat cancer, but aim to intercept and eliminate disease,” said Peter F. Lebowitz, M.D., Ph.D., Oncology Therapeutic Area Head, Janssen Research & Development. “We continue to investigate ways in which our medicines can potentially benefit patients at earlier stages of their disease, and we are excited to share emerging data at ASCO for our therapies.”

Key data presentations from our oncology pipeline, include:

- **abiraterone acetate:** Findings from the LATITUDE pivotal trial will provide the first look at Phase 3 results assessing abiraterone acetate plus prednisone in newly diagnosed patients with high-risk metastatic hormone-naïve prostate cancer (mHNPC) (Abstract LBA3).
    - These data will be featured in an ASCO Press Briefing from 8 – 9 a.m. CDT on Saturday, June 3rd and presented in the Plenary Session from 2:40 – 2:55 p.m. CDT on Sunday, June 4th. Data from the LATITUDE trial have also been selected for the Best of ASCO program.
- **daratumumab:** Follow-up data from the CASTOR/POLLUX pivotal trials will provide additional insights into the longer-term efficacy of the immunotherapy daratumumab in combination with lenalidomide plus dexamethasone (DRd), or bortezomib plus dexamethasone (DVd), in relapsed or refractory patients with multiple myeloma, based on cytogenetic risk (Abstract 8006).
    - These data will be presented in an Oral Presentation from 11:45 – 11:57 a.m. CDT on Sunday, June 4th.
- **daratumumab:** Phase 1b study results from the MMY1001 trial will provide an early look at the safety and efficacy of daratumumab in combination with carfilzomib, lenalidomide and dexamethasone (KRd) for patients with newly diagnosed multiple myeloma. These data examine daratumumab combination therapy for patients at an earlier stage of disease (Abstract 8000).
    - These data will be presented in an Oral Presentation from 9:45 – 9:57 a.m. CDT on Sunday, June 4th, and have been accepted for the Best of ASCO program.
- **ibrutinib:** Up to four-year follow-up data from the pivotal Phase 3 RESONATE study will shed light on the longer-term efficacy and safety of treatment with the BTK inhibitor ibrutinib in previously treated patients with chronic lymphocytic leukemia (CLL), including those with genetic abnormalities deletion 11q and deletion 17p, which put patients at risk for poor outcomes (Abstract 7510).
    - These data will be presented in a Poster Discussion Session from 1:15 – 2:30 p.m. CDT on Monday, June 5th.

A full list of company-sponsored abstracts to be presented at the meeting follows below:

Abstract No.	**Title**	**Date/Time**
abiraterone acetate		
Abstract #LBA3	LATITUDE: A Phase III double-blind, randomized trial of androgen deprivation therapy with abiraterone acetate plus prednisone or placebos in newly diagnosed high-risk metastatic hormone-naïve prostate cancer	Plenary Session Sunday, June 4th 2:40 – 2:55 p.m. CDT
Abstract #5007	Circulating tumor cell number as a response endpoint in metastatic castration resistant prostate cancer compared with PSA across 5 randomized Phase 3 Trials	Oral Presentation Saturday, June 3rd 3:27 – 3:39 p.m. CDT
Abstract # 5015	Clinical outcome of metastatic castration-resistant prostate cancer (mCRPC) patients (pts) with a post-treatment circulating tumor cell (CTC) of 0 vs CTC > 0: Post hoc analysis of COU-AA-301.	Poster Discussion Monday, June 5th 1:15 – 4:45 p.m. CDT
Abstract # 5036	Assessment of quality of life, cognitive function and depression in a randomized phase ii crossover study of abiraterone + prednisone vs enzalutamide for metastatic castrate-resistant prostate cancer	Poster Session Monday, June 5th 1:15 – 4:45 p.m. CDT
Abstract # 5028	Real-world outcomes in second-line treatment of metastatic	Poster Session

	castration-resistant prostate cancer: the prostate cancer registry	Monday, June 5th 1:15 – 4:45 p.m. CDT
daratumumab		
Abstract # 8000	Daratumumab (DARA) in combination with carfilzomib, lenalidomide, and dexamethasone (KRd) in patients (pts) with newly diagnosed multiple myeloma (MMY1001): an open-label, Phase 1b study	Oral Presentation Sunday, June 4th 9:45 – 9:57 a.m. CDT
Abstract # 8006	Efficacy of daratumumab in combination with lenalidomide plus dexamethasone (DRd) or bortezomib plus dexamethasone (DVd) in relapsed or refractory multiple myeloma (RRMM) based on cytogenetic risk status	Oral Presentation Sunday, June 4th 11:45 – 11:57 a.m. CDT
Abstract # TPS9102	Randomized, open-label Phase 1b/2 study of atezolizumab with or without daratumumab in previously treated advanced or metastatic non-small cell lung cancer (NSCLC)	Poster Session Saturday, June 3rd 8:00 – 11:30 a.m. CDT
Abstract # 8036	Daratumumab, bortezomib and dexamethasone (DVd) vs bortezomib and dexamethasone (Vd) in relapsed or refractory multiple myeloma (RRMM): efficacy and safety update (CASTOR)	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Abstract # 8042	Comparative efficacy of multiple myeloma therapies for treatment of first relapse – a systematic literature review and network meta-analysis	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Abstract # 8025	Daratumumab, lenalidomide, and dexamethasone (DRd) vs lenalidomide and dexamethasone (Rd) in relapsed or refractory multiple myeloma (RRMM): efficacy and safety update (POLLUX)	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Abstract # 8033	Safety and efficacy of daratumumab-based regimens in elderly patients (Pts) with relapsed or refractory multiple myeloma (RRMM): subgroup analysis of POLLUX and CASTOR	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
ibrutinib		
Abstract #7510	Long-term efficacy and safety with ibrutinib in previously treated chronic lymphocytic leukemia (CLL): up to four years follow-up of the RESONATE study	Poster Discussion Monday, June 5th 1:15 – 2:30 p.m. CDT
Abstract #TPS7072	A randomized, double-blind Phase 3 Study of ibrutinib versus placebo in combination with corticosteroids in patients with new onset chronic graft versus host disease (Trial in Progress)	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Abstract #7524	Ibrutinib vs chlorambucil: immunophenotypic and quantitative impacts on circulating immune cells in chronic lymphocytic leukemia (CLL)	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Abstract #TPS7576	A multicenter, randomized, double-blind, placebo-controlled Phase 3 study of the Bruton's Tyrosine Kinase (BTK) inhibitor, ibrutinib, in combination with rituximab versus placebo in combination with rituximab in patients with treatment-naïve follicular lymphoma	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Other		
Abstract #5027	Time to metastasis or death in non-metastatic castrate resistant prostate cancer patients by National Comprehensive Cancer Network risk groups	Poster Session Monday, June 5th 1:15 – 4:45 p.m. CDT
Abstract # 7561	Development of a clinical trial immunohistochemistry (IHC) assay using a novel antibody to CD38	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT
Abstract # 8046	Trends in survival and costs among US multiple myeloma patients	Poster Session Monday, June 5th 8:00 – 11:30 a.m. CDT

About ZYTIGA® (abiraterone acetate)

ZYTIGA® (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). ZYTIGA inhibits CYP17-mediated androgen production – which fuels prostate cancer growth – at three sources: in the testes, adrenals and the prostate tumor tissue – and has proven efficacy in patients with mCRPC who have progressed on androgen deprivation therapy.

Since its first approval in the U.S. in 2011, ZYTIGA has been approved in more than 104 countries. More than 290,000 men worldwide have received treatment with it, and it was the number one prescribed therapy in the U.S. for men with mCRPC in 2016.

Janssen is committed to supporting access to ZYTIGA for appropriate patients who are prescribed this medicine. ZytigaOne™ Support provides enhanced support to physician offices and personalized care coordination services to patients, including the ZytigaOne™ Instant Savings Program, which can help eligible commercially insured patients with out-of-pocket co-pays and coinsurance. For more information on ZytigaOne™ Support, contact 1-855-ZYTIGA-1.

For more information about ZYTIGA, visit www.ZYTIGA.com.

IMPORTANT SAFETY INFORMATION

Contraindications - ZYTIGA® (abiraterone acetate) is not indicated for use in women. ZYTIGA® can cause fetal harm (Pregnancy Category X) when administered to a pregnant woman and is contraindicated in women who are or may become pregnant.

Hypertension, Hypokalemia and Fluid Retention Due to Mineralocorticoid Excess - Use with caution in patients with a history of cardiovascular disease or with medical conditions that might be compromised by increases in blood pressure, hypokalemia, or fluid retention. ZYTIGA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Safety has not been established in patients with LVEF <50% or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) because these patients were excluded from these randomized clinical trials. Control hypertension and correct hypokalemia before and during treatment. Monitor blood pressure, serum potassium, and symptoms of fluid retention at least monthly.

Adrenocortical Insufficiency (AI) - AI was reported in patients receiving ZYTIGA® in combination with prednisone, after an interruption of daily steroids and/or with concurrent infection or stress. Use caution and monitor for symptoms and signs of AI if prednisone is stopped or withdrawn, if prednisone dose is reduced, or if the patient experiences unusual stress. Symptoms and signs of AI may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with ZYTIGA®. Perform appropriate tests, if

indicated, to confirm AI. Increased dosages of corticosteroids may be used before, during, and after stressful situations.

Hepatotoxicity - In postmarketing experience, there have been ZYTIGA®-associated severe hepatic toxicities, including fulminant hepatitis, acute liver failure and deaths. Monitor liver function and modify, withhold, or discontinue ZYTIGA® dosing as recommended (see Prescribing Information for more information). Measure serum transaminases [alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] and bilirubin levels prior to starting treatment with ZYTIGA®, every two weeks for the first three months of treatment, and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the upper limit of normal (ULN) or the bilirubin rises above three times the ULN, interrupt ZYTIGA® treatment and closely monitor liver function. Re-treatment with ZYTIGA® at a reduced dose level may take place only after return of liver function tests to the patient’s baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN.

Permanently discontinue ZYTIGA® for patients who develop a concurrent elevation of ALT greater than 3X ULN and total bilirubin greater than 2X ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

Adverse Reactions - The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

Drug Interactions - Based on in vitro data, ZYTIGA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during ZYTIGA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the ZYTIGA® dosing frequency only during the co-administration period [see Dosage and Administration (2.3)]. In a dedicated drug interaction trial, co-administration of ketoconazole, a strong inhibitor of CYP3A4, had no clinically meaningful effect on the pharmacokinetics of abiraterone.

ZYTIGA® is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid co-administration with CYP2D6 substrates with a narrow therapeutic index. If alternative treatments cannot be used, exercise caution and consider a dose reduction of the CYP2D6 substrate drug. In a CYP2C8 drug interaction trial in healthy subjects, the AUC of pioglitazone, a CYP2C8 substrate, was increased by 46% when administered with a single dose of ZYTIGA®. Patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with ZYTIGA®.

Use in Specific Populations - Do not use ZYTIGA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

About DARZALEX® (daratumumab) Injection, for Intravenous Infusion

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed cytolytic antibody approved anywhere in the world.[1] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[2] 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.[3] A subset of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by DARZALEX.[3] DARZALEX is being evaluated in a comprehensive clinical development program that includes five Phase 3 studies across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[4,5,6,7,8] Additional studies are ongoing or planned to assess its potential for a solid tumor indication and in other malignant and pre-malignant diseases in which CD38 is expressed, such as smoldering myeloma.[9,10,11] DARZALEX was the first cytolytic antibody to receive regulatory approval to treat relapsed or refractory multiple myeloma.[12]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS - None

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX can cause severe infusion reactions. Approximately half of all patients experienced a reaction, most during the first infusion. 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 for life-threatening (Grade 4) reactions. 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 – In patients who received Darzalex in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (92%), thrombocytopenia (73%), 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 were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%) and pyrexia (3%).

In patients who received Darzalex in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: thrombocytopenia (90%), neutropenia (58%), 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 were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%).

In patients who received Darzalex as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (60%), thrombocytopenia (48%), infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). Serious adverse reactions were reported in 51 (33%) patients. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%).

DRUG INTERACTIONS

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

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

About IMBRUVICA® (ibrutinib)

IMBRUVICA® was one of the first therapies to receive U.S. approval after having received the FDA's Breakthrough Therapy Designation. IMBRUVICA works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[13] The BTK protein transmits important signals that tell B cells to mature and produce antibodies and is needed by specific cancer cells to multiply and spread.[14,15] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.[15] For more information, visit www.IMBRUVICA.com.

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 up to 6% of patients. Bleeding events of any grade, including bruising and petechiae, occurred in approximately half 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 postsurgery depending upon the type of surgery and the risk of bleeding.

Infections - Fatal and nonfatal infections have occurred with IMBRUVICA® therapy. Grade 3 or greater infections occurred in 14% to 29% of patients. Cases of progressive multifocal leukoencephalopathy (PML) and *Pneumocystis jirovecii* pneumonia (PJP) have occurred in patients treated with IMBRUVICA®. Evaluate patients for fever and infections and treat appropriately.

Cytopenias - Treatment-emergent Grade 3 or 4 cytopenias including neutropenia (range, 13% to 29%), thrombocytopenia (range, 5% to 17%), and anemia (range, 0% to 13%) based on laboratory measurements occurred in patients treated with single agent IMBRUVICA®. Monitor complete blood counts monthly.

Atrial Fibrillation - Atrial fibrillation and atrial flutter (range, 6% to 9%) have occurred in patients treated with IMBRUVICA®, particularly in patients with cardiac risk factors, hypertension, acute infections, and a previous history of atrial fibrillation. Periodically monitor patients clinically for atrial fibrillation. Patients who develop arrhythmic symptoms (eg, palpitations, lightheadedness) or new-onset dyspnea should have an ECG performed. Atrial fibrillation should be managed appropriately and if it persists, consider the risks and benefits of IMBRUVICA® treatment and follow dose modification guidelines.

Hypertension - Hypertension (range, 6% to 17%) has occurred in patients treated with IMBRUVICA® with a median time to onset of 4.6 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 antihypertensive medications and/or initiate antihypertensive treatment as appropriate.

Second Primary Malignancies - Other malignancies (range, 3% to 16%) including non-skin carcinomas (range, 1% to 4%) have occurred in patients treated with IMBRUVICA®. The most frequent second primary malignancy was non-melanoma skin cancer (range, 2% to 13%).

Tumor Lysis Syndrome - Tumor lysis syndrome has been infrequently reported with IMBRUVICA® therapy. Assess the baseline risk (eg, 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

The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia* (61%), thrombocytopenia* (62%), diarrhea (43%), anemia* (41%), musculoskeletal pain (30%), rash (30%), nausea (29%), bruising (30%), fatigue (29%), hemorrhage (22%), and pyrexia (21%).

* Based on adverse reactions and/or laboratory measurements (noted as platelets, neutrophils, or hemoglobin decreased).

The most common Grade 3 or 4 non-hematologic adverse reactions (≥5%) in MCL patients were pneumonia (7%), abdominal pain (5%), atrial fibrillation (5%), diarrhea (5%), fatigue (5%), and skin infections (5%). The most common Grade 3 or 4 non-hematologic adverse reactions (≥5%) in MZL patients were pneumonia (10%), fatigue (6%), diarrhea (5%), rash (5%), and hypertension (5%).

Approximately 6% (CLL/SLL), 14% (MCL), 11% (WM) and 10% (MZL) of patients had a dose reduction due to adverse reactions. Approximately 4%-10% (CLL/SLL), 9% (MCL), and 9% (WM [6%] and MZL [13%]) of patients discontinued due to adverse reactions. Most common adverse reactions leading to discontinuation were pneumonia, hemorrhage, atrial fibrillation, rash, and neutropenia (1% each) in CLL/SLL patients and subdural hematoma (1.8%) in MCL patients. The most common adverse reactions leading to discontinuation were interstitial lung disease, diarrhea, and rash (1.6% each) in WM and MZL patients.

DRUG INTERACTIONS

CYP3A Inhibitors - Avoid coadministration with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA® dose.

CYP3A Inducers - Avoid coadministration with strong CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment - Avoid use in patients with moderate or severe baseline hepatic impairment. In patients with mild impairment, reduce IMBRUVICA® dose.

Please see Full Prescribing Information: https://www.imbruvica.com/prescribing-information.

About the Janssen Pharmaceutical Companies

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 www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

# # #

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. 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 and/or Johnson & Johnson.

Risks and uncertainties include, but are not limited to: challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

---

[1] Janssen Biotech, Inc. "DARZALEX (daratumumab) Approved by U.S. FDA: First Human Anti-CD38 Monoclonal Antibody Available for the Treatment of multiple Myeloma." Issued November 16, 2015.
[2] Fedele G et al. CD38 Ligation in Peripheral Blood Mononuclear Cells of Myeloma Patients Induces Release of Protumorigenic IL-6 and Impaired Secretion of IFNγ Cytokines and Proliferation. *Mediators Inflamm*. 2013;2013:564687
[3] DARZALEX Prescribing Information, June 2017
[4] Janssen Research & Development, LLC. A Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. Available from: https://clinicaltrials.gov/ct2/show/NCT02076009?term=mmy3003&rank=1 NLM Identifier: NCT02136134.
[5] Janssen Research & Development, LLC. Addition of Daratumumab to Combination of Bortezomib and Dexamethasone in Participants With Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. Available from: https://clinicaltrials.gov/ct2/show/NCT02136134?term=mmy3004&rank=1 NLM Identifier: NCT02076009.
[6] Janssen Research & Development, LLC. A Study to Evaluate Daratumumab in Transplant Eligible Participants With Previously Untreated Multiple Myeloma (Cassiopeia). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. Available from: https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmy3006&rank=2 NLM Identifier: NCT02541383.
[7] Janssen Research & Development, LLC. A Study of Combination of Daratumumab and Velcade (Bortezomib) Melphalan-Prednisone (DVMP) Compared to Velcade Melphalan-Prednisone (VMP) in Participants With Previously Untreated Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. https://clinicaltrials.gov/ct2/show/NCT02195479?term=mmy3007&rank=1 Identifier: NCT02195479.
[8] Janssen Research & Development, LLC. Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Participants With Previously Untreated Multiple MyelomaIn: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmy3008&rank=1Identifier: NCT02252172.
[9] Janssen Research & Development, LLC. "Janssen Announces the Initiation of Two Studies Evaluating Daratumumab (DARZALEX®) and Atezolizumab in Multiple Myeloma and Solid Tumor." Issued March 21, 2016
[10] Janssen Research & Development, LLC. A Study to Evaluate 3 Dose Schedules of Daratumumab in Participants With Smoldering Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. https://clinicaltrials.gov/ct2/show/NCT02316106?term=smm2001&rank=1 Identifier: NCT02316106.
[11] Janssen Research & Development, LLC. An Efficacy and Safety Proof of Concept Study of Daratumumab in Relapsed/Refractory Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, and Follicular Lymphoma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 Nov 11]. https://clinicaltrials.gov/ct2/show/NCT02413489?term=lym2001&rank=1 Identifier: NCT02413489.
[12] Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA in Combination with Two Standard of Care Regimens for the Treatment of Patients with Multiple Myeloma Who Have Received At Least One Prior Therapy." Issued November 21, 2017.
[13] IMBRUVICA Prescribing Information, January 2017.