



Media Inquiries:

Satu Glawe

Phone: +49-172-294-6264

Bernadette King

Phone: 1-215-778-3027

Investor Relations:

Lesley Fishman

Phone: 1-732-524-3922

U.S. Medical Inquiries:

1-800-526-7736

**Janssen to Present New Data in Urothelial, Hematologic and Prostate Cancers at
ASCO 2018, Including Best of ASCO Selections**

- *Urothelial – Phase 2 data for investigational urothelial cancer therapy, erdafitinib*
- *Hematologic – IMBRUVICA® Phase 3 data in first-line and relapsed/refractory Waldenström's macroglobulinemia; DARZALEX® Phase 1 combination data in relapsed/refractory multiple myeloma*
- *Prostate – ERLEADA™ Phase 3 data analyses evaluating new clinical trial endpoints in prostate cancer*

RARITAN, NJ, May 16, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced 21 company-sponsored abstracts will be presented at the [2018 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#) in Chicago, IL on June 1-5. New data analyses in support of a portfolio of products, including the investigational treatment erdafitinib, IMBRUVICA® (ibrutinib), DARZALEX® (daratumumab), ERLEADA™ (apalutamide) and ZYTIGA® (abiraterone acetate), will be highlighted across urothelial, hematologic and prostate cancers.

Notably, Phase 2 trial results for the investigational compound erdafitinib, which received U.S. Food and Drug Administration (FDA) [Breakthrough Therapy Designation](#), will be presented during an Oral Presentation on Sunday, June 3 ([Abstract #4503](#)). For hematologic cancers, Phase 3 data from the iNNOVATE study will provide the first look at IMBRUVICA plus rituximab versus placebo plus rituximab in patients with newly diagnosed and relapsed/refractory Waldenström's macroglobulinemia (WM) ([Abstract #8003](#)). In addition, Phase 2 data from the CAPTIVATE study will be presented evaluating IMBRUVICA plus venetoclax in first-line chronic lymphocytic leukemia (CLL) ([Abstract #7502](#)). Oral Presentations for erdafitinib and IMBRUVICA have been selected to be featured at the [Best of ASCO 2018 Meetings](#), which highlight cutting-edge science and reflect the leading research and strategies in oncology.

"We look forward to presenting the latest data from our robust oncology portfolio, which includes four innovative medicines that our expert team of scientists have developed to address the needs of patients living with hematologic malignancies or prostate cancer," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "In addition, new data for erdafitinib, a promising investigational therapy that received Breakthrough Therapy Designation for metastatic urothelial cancer from the U.S. FDA earlier this year, will be featured in an oral presentation, as one of several noteworthy selections from the portfolio."

Select data presentations include:

- **Erdafitinib:** Results from the primary analysis of the Phase 2 study of erdafitinib (ERDA; JNJ-42756493) in patients with metastatic or unresectable urothelial carcinoma (mUC) and Fibroblast Growth Factor Receptor alterations (FGFRalt).
 - These data will be featured in an Oral Presentation from 9:00 – 9:12 a.m. CDT on Sunday, June 3 ([Abstract #4503](#)) and have been selected for the [Best of ASCO 2018 Meetings](#).
- **IMBRUVICA:** Findings from the Phase 3 placebo-controlled iNNOVATE study will be presented, assessing IMBRUVICA plus rituximab versus placebo plus rituximab in patients with newly diagnosed and relapsed/refractory WM.*
 - These data will be featured in an Oral Presentation from 3:45 – 3:57 p.m. CDT on Friday, June 1 ([Abstract #8003](#)) and have been selected for the [Best of ASCO 2018 Meetings](#).
- **IMBRUVICA:** Early results from the Phase 2 CAPTIVATE study will be presented, evaluating IMBRUVICA in combination with venetoclax in first-line CLL.*
 - These data will be featured in an Oral Presentation from 10:09 – 10:21 a.m. CDT on Sunday, June 3 ([Abstract #7502](#)) and have been selected for the [Best of ASCO 2018 Meetings](#).

- **DARZALEX:** Phase 1 data from the MMY1001 study will report on the efficacy and safety of DARZALEX in combination with carfilzomib and dexamethasone in lenalidomide-refractory patients with relapsed multiple myeloma.
 - These data will be presented in an Oral Presentation from 3:09 – 3:21 p.m. CDT on Friday, June 1 ([Abstract #8002](#)).
- **DARZALEX:** Follow-up efficacy and safety data from the pivotal Phase 3 ALCYONE study will be presented for DARZALEX in combination with bortezomib, melphalan and prednisone in patients with newly diagnosed multiple myeloma who are transplant ineligible.
 - These data will be presented in a Poster Presentation from 8:00 – 11:30 a.m. CDT on Monday, June 4 ([Abstract #8031](#)).
- **DARZALEX:** Safety run-in results from the Phase 3 ANDROMEDA study will be presented evaluating the subcutaneous use of daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone in patients with newly diagnosed amyloid light chain (AL) amyloidosis. Amyloidosis is an incurable disease in which cells that normally produce antibodies make an abnormal protein that deposits in and causes damage to organs such as the heart and kidneys.¹
 - These data will be presented in a Poster Discussion Presentation from 3:00 – 4:15 p.m. CDT on Monday, June 4 ([Abstract #8011](#)).
- **ERLEADA:** New analyses from the pivotal Phase 3 SPARTAN clinical trial will be presented examining the relationship between time to metastasis (TTM) and site of metastases in patients with non-metastatic castration-resistant prostate cancer (nmCRPC).
 - These data will be presented in a Poster Presentation from 1:15 – 4:45 p.m. CDT on Saturday, June 2 ([Abstract #5033](#)).
- **ZYTIGA:** New findings from the pivotal Phase 3 LATITUDE clinical trial in patients with metastatic high-risk castration-sensitive prostate cancer (CSPC) will be presented.
 - These data will be presented in a Poster Presentation from 1:15 – 4:45 p.m. CDT on Saturday, June 2 ([Abstract #5028](#)).
- **Prostate Cancer:** New analysis exploring the association between metastasis-free survival (MFS) and overall survival (OS) will be presented in nmCRPC for the first time.
 - These data will be presented in a Poster Presentation from 1:15 – 4:45 p.m. CDT on Saturday, June 2 ([Abstract #5032](#)).

Additional abstracts to be presented include:

<u>Abstract No.</u>	<u>Title</u>	<u>Date/Time</u>
Erdafitinib Abstract #4503	First results from the primary analysis population of the Phase 2 study of erdafitinib (ERDA; JNJ-	Oral Presentation Sunday, June 3

	42756493) in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFRalt)	9:00 – 9:12 a.m. CDT
IMBRUVICA*		
Abstract #8003	Randomized Phase 3 trial of ibrutinib/rituximab vs rituximab in Waldenstrom’s macroglobulinemia	Oral Presentation Friday, June 1 3:45 – 3:57 p.m. CDT
Abstract #7502	Phase 2 CAPTIVATE results of ibrutinib (ibr) plus venetoclax (ven) in first-line chronic lymphocytic leukemia (CLL)	Oral Presentation Sunday, June 3 10:09 – 10:21 a.m. CDT
Abstract #7521	Prognostic role of beta-2 microglobulin (B2M) in relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) patients (pts) treated with ibrutinib (ibr)	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #2578	A multicenter study of the Bruton’s tyrosine kinase (BTK) inhibitor ibrutinib plus durvalumab in patients with relapsed/refractory (R/R) solid tumors	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
DARZALEX		
Abstract #8002	Daratumumab (DARA) in combination with carfilzomib and dexamethasone (D-Kd) in lenalidomide (Len)-refractory patients (Pts) with relapsed multiple myeloma (MM): Subgroup analysis of MMY1001	Oral Presentation Friday, June 1 3:09 – 3:21 p.m. CDT
Abstract #8013	Subcutaneous daratumumab (DARA) in patients (Pts) with relapsed or refractory multiple myeloma (RRMM): Part 2 update of the open-label, multicenter, dose escalation Phase 1b study (PAVO)	Poster Discussion Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #8011	Subcutaneous daratumumab (DARA SC) plus cyclophosphamide, bortezomib, and dexamethasone (CyBorD) in patients (Pts) with newly diagnosed amyloid light chain (AL) amyloidosis: Safety run-in results of ANDROMEDA	Poster Discussion Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #8031	Daratumumab plus bortezomib-melphalan-prednisone (VMP) in elderly (≥ 75 y) patients (Pts) with newly diagnosed multiple myeloma (NDMM) ineligible for transplantation (ALCYONE)	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #TPS8059	Pomalidomide and dexamethasone (pom-dex) with or without daratumumab (DARA) in patients (pts) with relapsed or refractory multiple myeloma (RRMM): a multicenter, randomized, Phase 3 study (APOLLO)	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #TPS8058	Randomized, open-label, non-inferiority, Phase 3 study of subcutaneous (SC) versus intravenous (IV) daratumumab (DARA) administration in patients with relapsed or refractory multiple myeloma (RRMM): COLUMBA	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #8042	Health-related quality of life in patients with newly diagnosed multiple myeloma who are ineligible for stem cell transplantation: Results from the ALCYONE trial	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
Abstract #TPS8062	Randomized, open-label, Phase 3 study of subcutaneous daratumumab (DARA SC) versus active monitoring in patients (Pts) with high-risk smoldering multiple myeloma (SMM): AQUILA	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT

Abstract #TPS8057	Randomized, open-label, Phase 2/3 study of daratumumab (DARA) with or without JNJ-63723283, an anti-PD-1 monoclonal antibody, in relapsed/refractory multiple myeloma (RRMM)	Poster Session Monday, June 4 8:00 – 11:30 a.m. CDT
ERLEADA		
Abstract #5033	Relationship of time to metastasis (TTM) and site of metastases in patients (pts) with nonmetastatic castration-resistant prostate cancer (nmCRPC): Results from the Phase 3 SPARTAN trial	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT
Abstract #5034	Predicting disease progression in patients (pts) with nonmetastatic castration-resistant prostate cancer (nmCRPC): An analysis from the Phase 3 SPARTAN trial	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT
ZYTIGA		
Abstract #5028	Subsequent treatment after abiraterone acetate + prednisone (AA + P) in patients (pts) with newly diagnosed high-risk metastatic castration-naïve prostate cancer (NDx-HR mCNPC): detailed analyses from the Phase 3 LATITUDE trial	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT
Abstract #5023	Longer term preplanned efficacy and safety analysis of abiraterone acetate + prednisone (AA + P) in patients (pts) with newly diagnosed high-risk metastatic castration-naïve prostate cancer (NDx-HR mCNPC) from the Phase 3 LATITUDE trial	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT
Abstract #5067	Clinical qualification of plasma androgen receptor (pAR) status and outcome on abiraterone acetate (AA) plus prednisone or dexamethasone (+P/D) in a Phase 2 multi-institutional study in metastatic castration resistant prostate cancer (mCRPC)	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT
Abstract #5038	A transcriptome analysis of castration resistant prostate cancer metastases in a prospective cohort study reveals high expression of AKT pathway genes predictive of long term response to abiraterone acetate/prednisone	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT
Prostate Cancer		
Abstract #5032	Association of metastasis-free survival (MFS) and overall survival (OS) in nonmetastatic castration-resistant prostate cancer (nmCRPC)	Poster Discussion Saturday, June 2 1:15 – 4:45 p.m. CDT

*Abstracts were submitted by IMBRUVICA co-developer partner, Pharmacyclics, an AbbVie company.

About Erdafitinib

Erdafitinib is a once-daily pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated by Janssen Research and Development in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer and other solid tumors.² FGFRs are a family of receptor tyrosine kinases, which may be upregulated in various tumor cell types and may be involved in tumor cell proliferation, tumor angiogenesis and tumor cell survival.³ In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Therapeutics Ltd. to develop and commercialize erdafitinib.

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.⁵ Subsets of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by DARZALEX. DARZALEX is approved for use across multiple lines of therapy and 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 INFORMATION⁴

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 bortezomib, melphalan, and prednisone, the most frequently reported adverse reactions (incidence $\geq 20\%$) were: upper respiratory tract infection (48%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions ($\geq 2\%$ greater 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 $\geq 20\%$ were thrombocytopenia (38%), neutropenia (44%), and lymphopenia (58%).

In patients who received DARZALEX in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence $\geq 20\%$) 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 $\geq 20\%$) 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 $\geq 20\%$) 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%).

In patients who received DARZALEX in combination with pomalidomide and dexamethasone, the most frequent adverse reactions ($\geq 20\%$) were infusion reactions (50%), diarrhea (38%), constipation (33%), nausea (30%), vomiting (21%), fatigue (50%), pyrexia (25%), upper respiratory tract infection (50%), muscle spasms (26%), back pain (25%), arthralgia (22%), dizziness (21%), insomnia (23%), cough (43%) and dyspnea (33%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions reported in $\geq 5\%$ patients included pneumonia (7%).

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.

About ERLEADA

ERLEADA (apalutamide) is an androgen receptor (AR) inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and was approved by the FDA on [February 14, 2018](#) as the first approved treatment for this disease state.¹⁷

ERLEADA is a next-generation AR inhibitor that binds directly to the ligand-binding domain of the AR. ERLEADA inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription. A major metabolite, N-desmethyl apalutamide, is a less potent inhibitor of AR, and exhibited one-third the activity of ERLEADA in an in vitro transcriptional reporter assay. ERLEADA administration caused decreased tumor cell proliferation and increased apoptosis leading to decreased tumor volume in mouse xenograft models of prostate cancer.¹⁸

Full prescribing information is available at www.ERLEADA.com.

ERLEADA IMPORTANT SAFETY INFORMATION¹⁸

Do not take ERLEADA™ (apalutamide) if you:

- are pregnant or may become pregnant. ERLEADA™ may harm your unborn baby.
- are female. ERLEADA™ is not for use in women.

Before taking ERLEADA™, tell your healthcare provider about all your medical conditions, including if you:

- have a history of seizures, brain injury, stroke, or brain tumors.
- have a partner who is pregnant or may become pregnant. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with ERLEADA™. If your sexual partner may become pregnant, an effective birth control (contraception) must be used during and for 3 months after treatment. Talk with your healthcare provider if you have questions about birth control.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ERLEADA™ can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ERLEADA™.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ERLEADA™?

- Take ERLEADA™ exactly as your healthcare provider tells you.
- Take your prescribed dose of ERLEADA™ 1 time a day, at the same time each day.
- Take ERLEADA™ with or without food.
- Swallow ERLEADA™ tablets whole.
- Your healthcare provider may change your dose if needed.
- Do not stop taking your prescribed dose of ERLEADA™ without talking with your healthcare provider first.
- If you miss a dose of ERLEADA™, take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day. You should not take extra tablets to make up the missed dose.
- You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with ERLEADA™ unless you had a surgery to lower the amount of testosterone in your body (surgical castration).
- If you take too much ERLEADA™, call your healthcare provider or go to the nearest hospital emergency room.

Your healthcare provider may do blood tests to check for side effects.

What are the possible side effects of ERLEADA™?

ERLEADA™ may cause serious side effects including:

- **Falls and fractures.** ERLEADA™ treatment can cause bones and muscles to weaken and may increase your risk for falls and fractures. Falls and fractures have happened in people during treatment with ERLEADA™. Falls were not caused by loss of consciousness (fainting) or seizures. Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLEADA™.
- **Seizure.** If you take ERLEADA™, you may be at risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have a loss of consciousness or seizure. Your healthcare provider will stop ERLEADA™ if you have a seizure during treatment.

The most common side effects of ERLEADA™ include:

- feeling very tired
- high blood pressure
- rash
- diarrhea
- nausea
- decreased appetite
- weight loss
- joint pain
- fall
- hot flash
- bone injury (fracture)
- swollen hands, ankles, or feet

ERLEADA™ may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility. Do not donate sperm during treatment with ERLEADA™ and for 3 months after the last dose of ERLEADA™.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ERLEADA™.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the full [Prescribing Information](#) for ERLEADA™.

INDICATION

What is ERLEADA™?

ERLEADA™ is a prescription medicine used to treat prostate cancer that has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone.

It is not known if ERLEADA™ is safe or effective in children.

About IMBRUVICA

IMBRUVICA (ibrutinib) was one of the first therapies to receive U.S. approval after having received the FDA's Breakthrough Therapy Designation.¹⁹ IMBRUVICA works by blocking a specific protein called Bruton's tyrosine kinase (BTK). 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.²⁰ IMBRUVICA targets and blocks BTK, inhibiting the survival and spread of cancer cells, and impacting signaling associated with other serious conditions. Worldwide, IMBRUVICA was used to treat more than 100,000 patients to date. For more information, visit www.IMBRUVICA.com.

Additional Information about IMBRUVICA

INDICATIONS

IMBRUVICA is indicated to treat adults with²¹

- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)
- Mantle cell lymphoma (MCL) patients who have received at least one prior therapy
 - Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Marginal zone lymphoma (MZL) patients who require systemic therapy and have received at least one prior anti-CD20-based therapy
 - Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Chronic Graft-Versus-Host Disease (cGVHD) patients who failed one or more lines of systemic therapy

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 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 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 14% to 29% of patients. 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 (range, 13 to 29%), thrombocytopenia (range, 5 to 17%), and anemia (range, 0 to 13%) 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 to 1% of patients, and Grade 3 or greater atrial fibrillation and atrial flutter occurred in 0 to 6% of patients. 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 (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 anti-hypertensive medications and/or initiate anti-hypertensive 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 (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 ($\geq 20\%$) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were thrombocytopenia (62%)*, neutropenia (61%)*, diarrhea (43%), anemia (41%)*, musculoskeletal pain (30%), bruising (30%), rash (30%), fatigue (29%), nausea (29%), hemorrhage (22%), and pyrexia (21%).

The most common Grade 3 or 4 adverse reactions ($\geq 5\%$) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia (39%)*, thrombocytopenia (16%)*, and pneumonia (10%).

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.

cGVHD: The most common adverse reactions ($\geq 20\%$) 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 ($\geq 5\%$) 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 adjustment 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 see Full Prescribing Information: <https://www.imbruvica.com/prescribing-information>.

About ZYTIGA ²²

ZYTIGA® (abiraterone acetate) in combination with prednisone is indicated for the treatment of patients

- with metastatic castration-resistant prostate cancer (CRPC)
- with metastatic high-risk castration-sensitive prostate cancer (CSPC)

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

ZYTIGA IMPORTANT SAFETY INFORMATION

Contraindications - ZYTIGA (abiraterone acetate) can cause fetal harm and potential loss of pregnancy.

Hypertension, Hypokalemia and Fluid Retention Due to Mineralocorticoid Excess -

ZYTIGA may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition [see *Clinical Pharmacology (12.1)*]. Monitor patients for hypertension, hypokalemia, and fluid retention at least once a month. Control hypertension and correct hypokalemia before and during treatment.

Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia or fluid retention, such as those with heart failure, recent myocardial infarction, cardiovascular disease, or ventricular arrhythmia. The safety of ZYTIGA in patients with left ventricular ejection fraction <50% or New York Heart Association (NYHA) Class III or IV heart failure (in COU-AA-301) or NYHA Class II to IV heart failure (in COU-AA-302 and LATITUDE) has not been established because these patients were excluded from these randomized clinical trials [see *Clinical Studies (14)*].

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. Monitor patients 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. Measure serum transaminases alanine aminotransferase (ALT and AST) and bilirubin levels prior to starting treatment with ZYTIGA, every two weeks for the first three months of treatment, and monthly thereafter. In patients with baseline moderate hepatic impairment receiving a reduced ZYTIGA[®] dose of 250 mg, measure ALT, AST, and bilirubin prior to the start of treatment, every week for the first month, every two weeks for the following two 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 [*See Dosage and Administration (2.4)*].

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.

The safety of ZYTIGA re-treatment of patients who develop AST or ALT greater than or equal to 20X ULN and/or bilirubin greater than or equal to 10X ULN is unknown.

Adverse Reactions - The most common adverse reactions ($\geq 10\%$) are fatigue, arthralgia, hypertension, nausea, edema, hypokalemia, hot flush, diarrhea, vomiting, upper respiratory tract infection, cough, and headache.

The most common laboratory abnormalities ($>20\%$) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia 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, 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

- **Females and Males of Reproductive Potential: Advise males with female partners of reproductive potential to use effective contraception.**
- Do not use ZYTIGA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

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 www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

#

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the investigational treatment erdafitinib, IMBRUVICA® (ibrutinib), DARZALEX® (daratumumab), ERLEADA™ (apalutamide), and ZYTIGA® (abiraterone acetate). 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, the Janssen Pharmaceutical Companies of Johnson & Johnson 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 subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

¹ Palladini G. And Merlini G. What is New in Diagnosis and Management of Light Chain Amyloidosis? 2016 128: 159-168. <http://www.bloodjournal.org/content/128/2/159?sso-checked=true>. Accessed April 2018.

² Tabernero J, Bahleda R, Dienstmann R, Infante JR, Mita A, Italiano A, Calvo E, Moreno V, Adamo B, Gazzah A, et al. Phase I dose-escalation study of JNJ-42756493, an oral pan-fibroblast growth factor receptor inhibitor, in patients with advanced solid tumors. *J Clin Oncol*. 2015;33:3401–3408. doi: 10.1200/JCO.2014.60.7341.

³ Dienstmann R, Rodon J, Prat A, et al. Genomic aberrations in the FGFR pathway: Opportunities for targeted therapies in solid tumors. *Ann Oncol*. 2014;25:552–563.

⁴ DARZALEX Prescribing Information, May 2018.

⁵ Fedele G et al. CD38 Ligation in Peripheral Blood Mononuclear Cells of Myeloma Patients Induces Release of Protumorigenic IL-6 and Impaired Secretion of IFN γ Cytokines and Proliferation. *Mediators Inflamm*. 2013;2013:564687.

⁶ 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 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02076009?term=mmy3003&rank=1> NLM Identifier: NCT02136134.

⁷ 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 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02136134?term=mmy3004&rank=1> NLM Identifier: NCT02076009.

⁸ 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 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmy3006&rank=2> NLM Identifier: NCT02541383.

⁹ 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 2018 March 19].

-
- ¹⁰ Janssen Research & Development, LLC. Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Participants With Previously Untreated Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmy3008&rank=1> Identifier: NCT02252172.
- ¹¹ Janssen Research & Development, LLC. A Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination With VMP (D-VMP), in Participants With Previously Untreated Multiple Myeloma Who Are Ineligible for High-Dose Therapy (Asia Pacific Region). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19] Available at: <https://clinicaltrials.gov/ct2/show/NCT03217812?term=MMY3011&rank=1> Identifier: NCT03217812.
- ¹² European Myeloma Network. Compare Progression Free Survival Btw Daratumumab/Pomalidomide/Dexamethasone vs Pomalidomide/Dexamethasone (EMN14). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 28 June 2017] Available at: <https://clinicaltrials.gov/ct2/show/NCT03180736?term=MMY3013&rank=2> Identifier: NCT03180736
- ¹³ Amgen. Study of Carfilzomib, Daratumumab and Dexamethasone for Patients With Relapsed and/or Refractory Multiple Myeloma. (CANDOR). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19] Available at: <https://clinicaltrials.gov/ct2/show/NCT03158688?term=NCT03158688&rank=1> Identifier: NCT03158688.
- ¹⁴ 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.
- ¹⁵ 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 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02316106?term=smm2001&rank=1> Identifier: NCT02316106.
- ¹⁶ 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 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02413489?term=lym2001&rank=1> Identifier: NCT02413489
- ¹⁷ U.S. Food & Drug Administration. FDA approves new treatment for a certain type of prostate cancer using novel clinical trial endpoint. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm596768.htm>. Accessed May 2018.
- ¹⁸ ERLEADA Prescribing Information, February 2018.
- ¹⁹ IMBRUVICA U.S. Prescribing Information, February 2018
- ²⁰ Genetics Home Reference. Isolated growth hormone deficiency. <http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency>. Accessed May 2018.
- ²¹ Genetics Home Reference. Isolated growth hormone deficiency. <http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency>. Accessed May 2018.
- ²² ZYTIGA Prescribing Information, March 2018.