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Janssen Highlights Innovative Oncology Portfolio and Pipeline of Oral, Biologic and Cell Therapies Through ASCO20 Virtual Scientific Program

Presentations Distinguish Robust, Diverse Oncology Portfolio and Pipeline Across Hematologic Malignancies, Prostate Cancer and Solid Tumors

RARITAN, N.J., May 29, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the latest research from its innovative oncology portfolio and pipeline of novel oral, biologic and cell therapies is now available as part of the American Society of Clinical Oncology (ASCO) Virtual Scientific Program. Among the data presented are longer-term results from the JNJ-4528 BCMA-directed CAR-T therapy Phase 1b/2 CARTITUDE-1 study in relapsed or refractory multiple myeloma (RRMM); results from the ERLEADA® (apalutamide) Phase 3 SPARTAN study reporting overall survival (OS) in non-metastatic castration-resistant prostate cancer (nmCRPC); and initial results from Phase 1 studies of amivantamab (EGFRxMET bispecific antibody) in non-small cell lung cancer (NSCLC); and teclistamab (BCMAxCD3 bispecific antibody) in RRMM. Further information about these studies and the science that Janssen is championing for patients is available via the Janssen Oncology Virtual Newsroom.

"Through our discovery, development and collaborative efforts, we continue to advance a deep, differentiated portfolio and pipeline of small molecules, biologics and cell therapies for patients with hematologic malignancies, prostate cancer, lung cancer and bladder cancer," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research &

Development, LLC. “We’re proud to have achieved nine oncology drug approvals since 2011, 10 Breakthrough Therapy Designations and to be advancing six novel bispecific antibodies in the clinic. Our strategy is rooted in a deep understanding of disease, a scientific approach to transformational regimens and a movement towards cancer interception as we aim to realize our vision of the elimination of cancer.”

Key Janssen Data Presentations Include:

Longer-Term Follow-Up Data for BCMA-Targeted CAR-T Therapy JNJ-4528 Show Early, Deep and Durable Responses in Heavily Pretreated Patients with Multiple Myeloma
An oral presentation of updated results from the Phase 1b/2 CARTITUDE-1 study of JNJ-4528 in patients with RRMM (Abstract #8505).

Final Analysis of Phase 3 SPARTAN Study Marks Second ERLEADA® Phase 3 Registrational Study to Show Overall Survival Benefit
The pre-planned final analysis demonstrating OS results from the Phase 3 SPARTAN study evaluating ERLEADA® in combination with androgen deprivation therapy (ADT) in patients with nmCRPC who are at high risk of metastases (Abstract #5516).

Amivantamab Data in the Treatment of Patients with Advanced Non-Small Cell Lung Cancer Harboring Exon 20 Insertion Mutations
Results from the Phase 1 CHRYSALIS study of amivantamab in patients with metastatic NSCLC with EGFR Exon 20 insertion mutations (Abstract #9512), which served as the basis of a U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation as announced in March.

First Data from Phase 1 Study of BCMAxCD3 Bispecific Teclistamab in Patients with Relapsed or Refractory Multiple Myeloma
An oral presentation of the first data from the Phase 1 study of teclistamab (Abstract #100), an investigational bispecific antibody targeting both BCMA and CD3 receptors on T-cells, in the treatment of patients with RRMM.

Data for IMBRUVICA® (ibrutinib), recently approved for a subsequent chronic lymphocytic leukemia indication, and DARZALEX *FASPRO™* (daratumumab and hyaluronidase-fihj), a new subcutaneous formulation recently approved for the treatment of multiple myeloma, will also be presented during the ASCO Virtual Scientific Program.

All Janssen-sponsored abstracts presented are listed below and abstracts presented for ZYTIGA® (abiraterone acetate) are available through the ASCO abstract database here.

Abstract No.	Title
Portfolio Products	
ERLEADA® (apalutamide)	
	Poster Discussion
Abstract #5516	Final Survival Results From SPARTAN, a Phase 3 Study of Apalutamide vs Placebo in Patients with nmCRPC
	Poster Presentations
Abstract #5535	Molecular Determinants of Outcome for mCSPC with Addition of Apalutamide or Placebo to Androgen Deprivation Therapy in TITAN
Abstract #5541	PSA Kinetics in Patients with Advanced Prostate Cancer Treated with Apalutamide: Results from the TITAN and SPARTAN Studies
Abstract #5521	Molecular Determinants of PSA Kinetics and Clinical Response to Apalutamide in Patients with nmCRPC in SPARTAN
DARZALEX® (daratumumab) and DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj)	
	Poster Presentations
Abstract #8537	Corticosteroid Tapering in Patients with Relapsed or Refractory Multiple Myeloma (RRMM) Receiving Subcutaneous Daratumumab: Part 3 of the Open-label, Multicenter, Phase 1b PAVO Study
Abstract #8538	Daratumumab + Bortezomib, Thalidomide, and Dexamethasone (D-VTd) in Transplant-eligible Newly Diagnosed Multiple Myeloma: Baseline slimCRAB-based Subgroup Analysis of CASSIOPEIA
Abstract #TPS8553	Subcutaneous Daratumumab in Patients with Multiple Myeloma Who Have Been Previously Treated with Intravenous Daratumumab: A Multicenter, Randomized, Phase 2 Study (LYNX)
Abstract #8526	Efficacy and Safety of Carfilzomib, Dexamethasone, Daratumumab (DKd) Twice-Weekly at 56 mg/m2 and Once-Weekly at 70 mg/m2 in RRMM: Cross-Study Comparison of CANDOR and MY1001*
	Publication
Abstract #e20563	Health Related Quality of Life (HRQoL) Outcomes from the Phase 3 CANDOR Study Comparing Carfilzomib, Dexamethasone, and Daratumumab (DKd) to Carfilzomib and Dexamethasone (Kd) in Patients with RRMM*
IMBRUVICA® (ibrutinib)	
	Poster Presentation
Abstract #8036	Clinical Activity of Cirmtuzumab, an Anti-ROR1 Antibody, in Combination with Ibrutinib; Interim Results of a Phase 1b/2 Study in MCL or CLL**
	Publications
Abstract #e20004	Toxicity Burden in Older Patients with CLL Receiving Bendamustine with Rituximab (BR) or Ibrutinib Regimens: Alliance A041202**
Abstract #e19354	Real-World Healthcare Resource Utilization (HRU)/Costs associated with Venetoclax Treatment among CLL/SLL Patients

Abstract #e19408	Real-world HRU and Costs among Relapsed/Refractory Mantle Cell Lymphoma Patients Receiving Ibrutinib or Chemoimmunotherapy (CIT)
BALVERSA™ (erdafitinib)	
Poster Discussion	
Abstract #5015	BLC2001 Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma (UC): Long-Term Outcomes in BLC2001
Poster Presentations	
Abstract #5026	Clinical Outcomes and Economic Burden for Bladder Cancer Patients: An Analysis from a Swedish Cancer Registry
Abstract #3055	Evolving Development of PD-1 Therapy: Cetrelimab (JNJ-63723283) from Monotherapy to Combination with Erdafitinib
Publication	
Abstract #e19144	Use of a Dynamic Disease Progression Model to Estimate Prevalence and Prognosis for Patients with UC in the U.S.
Late-Stage Pipeline	
JNJ-4528	
Oral Presentation	
Abstract #8505	Update of CARTITUDE-1: A Phase 1B/2 Study of JNJ-4528, a BCMA-Directed CAR-T Cell Therapy, in RRMM
Publication	
Abstract #e20539	Medical Resource Utilization Among Multiple Myeloma Patients who were Triple-exposed to a Proteasome Inhibitor, an Immunomodulatory Agent, and Daratumumab
Abstract #e20540	Patient Characteristics and Treatment Patterns in RRMM Patients After Exposure to a Proteasome Inhibitor, an Immunomodulatory Agent and Daratumumab
Abstract #e20543	Treatment Patterns in Multiple Myeloma: Real-World Experience of the Triple Class Exposed Patient
Amivantamab	
Poster Presentation	
Abstract #9512	Amivantamab, an Anti-EGFR-MET Bispecific Antibody, in Patients with EGFR Exon 20 Insertion-Mutated NSCLC
Niraparib	
Poster Presentations	
Abstract #TPS5588	A Phase 3 Randomized, Placebo-Controlled, Double-Blind Study of Niraparib Plus Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Patients with Metastatic Prostate Cancer (MAGNITUDE)
Abstract #5562	Association of Detectable Levels of Circulating Tumor DNA (ctDNA) with Disease Burden in Prostate Cancer
Early-Stage Pipeline	
Teclistamab	
Oral Presentation	

Abstract #100	Phase 1 Study of Teclistamab, a Humanized BCMA x CD3 Bispecific Antibody, in RRMM
Cusatuzumab	
Poster Presentation	
Abstract #TPS7565	CULMINATE: A Phase 2 Study of Cusatuzumab + Azacitidine in Patients with Newly Diagnosed Acute Myeloid Leukemia, Ineligible for Intensive Chemotherapy
Lazertinib	
Poster Presentations	
Abstract #9571	Intracranial Anti-Tumor Activity of Lazertinib in Patients with Advanced NSCLC Who Progressed After Prior EGFR TKI Therapy: Data from a Phase 1/2 Study±
Abstract #9601	ctDNA Resistance Landscape of Lazertinib, a Third-Generation EGFR Tyrosine Kinase Inhibitor±

* Abstracts submitted by Amgen in collaboration with Janssen Oncology

± Abstract submitted by Yuhan Corporation, which entered into a license and collaboration agreement with Janssen Biotech, Inc. for the development of lazertinib

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

About JNJ-4528

JNJ-4528 (LCAR-B38M) is an investigational CAR-T therapy for the treatment of patients with RRMM. In December 2017, Janssen entered into an exclusive worldwide license and collaboration agreement with Legend Biotech to develop and commercialize JNJ-4528. In May 2018, Janssen initiated a Phase 1b/2 trial (NCT03548207) to evaluate the efficacy and safety of JNJ-4528 in adults with RRMM, informed by the LEGEND-2 study results.

In December 2019, Janssen announced receipt of a Breakthrough Therapy Designation from the U.S. FDA, which is granted to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. In February 2019, the U.S. FDA granted Janssen an Orphan Drug Designation for JNJ-4528, and in February 2020, the European Commission granted Janssen an orphan designation for JNJ-4528. In February 2019, JNJ-4528 was granted PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA).

About ERLEADA®

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with nonmetastatic castration-sensitive prostate cancer (nmCRPC) and for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).[1] ERLEADA® received U.S. FDA approval for nmCRPC in February 2018, and was approved for mCSPC in September 2019.[3]

For more information, visit www.ERLEADA.com.

About Amivantamab

Amivantamab (JNJ-6372) is an investigational EGFRxMET bispecific antibody with immune cell-directing activity that targets activating and resistant EGFR and MET mutations and amplifications.[2,3] The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform. Amivantamab is being explored as both a monotherapy and combination therapy for patients with NSCLC who harbor genetic alterations. In March 2020, the U.S. FDA granted Breakthrough Therapy Designation for amivantamab for the treatment of patients with metastatic NSCLC with EGFR Exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy.

About Teclistamab

Teclistamab (JNJ-7957) is an investigational bispecific antibody targeting both BCMA and CD3. CD3 is involved in activating the immune system's response to fight infection, and BCMA is expressed at significantly higher levels in people with multiple myeloma.[4,5,6,7,8] Teclistamab redirects CD3 T-cells to BCMA-expressing myeloma cells to induce cytotoxicity of the targeted cells.[4,5] Results from preclinical studies demonstrate that teclistamab kills myeloma cell lines and myeloma bone marrow cells from heavily pretreated patients.[5]

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

About DARZALEX® and DARZALEX *FASPRO™*

DARZALEX® has been approved in seven indications, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.[9,10,11,12,13,14] DARZALEX *FASPRO™* received FDA approval on May 1, 2020 in five indications, two of which are in the frontline setting in newly diagnosed patients who are transplant ineligible. In August 2012, Janssen entered into an exclusive global license and development agreement with Genmab A/S to develop, manufacture, and commercialize DARZALEX®.[15]

For more information, visit www.DARZALEX.com.

About IMBRUVICA®

IMBRUVICA® is a once-a-day, first-in-class Bruton's tyrosine kinase (BTK) inhibitor that is administered orally, and is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company. IMBRUVICA® is indicated for adults in six disease areas, including five hematologic cancers and chronic graft-versus-host disease (cGVHD).[16]

For more information, visit www.IMBRUVICA.com.

About BALVERSA™

BALVERSA™ (erdafitinib) is a once-daily, oral fibroblast growth factor receptor (FGFR) kinase inhibitor indicated for the treatment of adults who have locally advanced or metastatic urothelial cancer (UC) that has susceptible FGFR3 or FGFR2 genetic alterations and who have progressed during or following at least one line of platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.[17] In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize BALVERSA™.

For more information, visit www.BALVERSA.com.

About Niraparib

Niraparib is an orally-administered selective poly ADP-ribose polymerase (PARP) inhibitor that is currently being studied by Janssen for the treatment of patients with prostate cancer. In October 2019, niraparib received Breakthrough Therapy Designation from the U.S. FDA based on the Phase 2 GALAHAD study in patients with mCRPC.

In April 2016, Janssen entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (now GSK),[18] for exclusive rights to niraparib in prostate cancer. In the U.S., niraparib is indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy; for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy; for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation, or genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy. Niraparib is currently marketed by GSK as ZEJULA®.[18]

For more information, visit www.ZEJULA.com.

About Cusatuzumab

Cusatuzumab, also known as ARGX-110, is an investigational antibody that targets CD70, an immune target involved in hematological malignancies. Cusatuzumab is being explored as a foundation therapy for the treatment of acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). In December 2018, Cilag GmbH International, an affiliate of Janssen entered into a worldwide collaboration and license agreement with argenx BVBA and argenx SE, to develop and commercialize cusatuzumab.[19]

ERLEADA® IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Ischemic cardiovascular events — In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 4% of patients treated with ERLEADA® and 3% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4% of patients treated with ERLEADA® and 2% of patients treated with placebo. Across the SPARTAN and TITAN studies, 6 patients (0.5%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with current evidence of unstable angina, myocardial infarction, or congestive heart failure within six months of randomization were excluded from the SPARTAN and TITAN studies.

Ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone targeted agents.

Falls — In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared to 9% of patients treated with placebo. Falls were not associated with loss

of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

Seizure — In two randomized studies (SPARTAN and TITAN), five patients (0.4%) treated with ERLEADA® and one patient treated with placebo (0.1%) experienced a seizure. Permanently discontinue ERLEADA® in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with ERLEADA®. Advise patients of the risk of developing a seizure while receiving ERLEADA® and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® *[see Use in Specific Populations (8.1, 8.3)]*.

ADVERSE REACTIONS

Adverse Reactions — The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥ 2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea and fracture.

Laboratory Abnormalities — All Grades (Grade 3-4)

- Hematology — In TITAN study, white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In SPARTAN study anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA® 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA® 41% (2%), placebo 21% (2%)
- Chemistry — In TITAN study, hypertriglyceridemia ERLEADA® 17% (3%), placebo 12% (2%). In SPARTAN study hypercholesterolemia ERLEADA® 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1%); hypertriglyceridemia ERLEADA® 67% (2%), placebo 49% (0.8%); hyperkalemia ERLEADA® 32% (2%), placebo 22% (0.5%).

Rash — In two randomized studies, rash was most commonly described as macular or maculo-papular. Adverse reactions of rash were 26% with ERLEADA® versus 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) versus placebo (0.5%).

The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines, topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 28% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

Hypothyroidism — In two randomized studies hypothyroidism, was reported for 8% of patients treated with ERLEADA® and 2% of patients treated with placebo based on assessments of thyroid-stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA® and 7% of patients treated with placebo. The median onset was at the first scheduled assessment. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose-adjusted.

DRUG INTERACTIONS

Effect of Other Drugs on ERLEADA® — Co-administration of a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA® dose based on tolerability *[see Dosage and Administration (2.2)].*

Effect of ERLEADA® on Other Drugs — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

P-gp, BCRP or OATP1B1 substrates — Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

Please see the full Prescribing Information for ERLEADA®

DARZALEX *FASPRO™* IMPORTANT SAFETY IMFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*™.

Systemic Reactions

In a pooled safety population of 490 patients who received DARZALEX *FASPRO*™ as monotherapy or in combination, 11% of patients experienced a systemic administration-related reaction (Grade 2: 3.9%, Grade 3: 1.4%). Systemic administration-related reactions occurred in 10% of patients with the first injection, 0.2% with the second injection, and cumulatively 0.8% with subsequent injections. The median time to onset was 3.7 hours (range: 9 minutes to 3.5 days). Of the 84 systemic administration-related reactions that occurred in 52 patients, 73 (87%) occurred on the day of DARZALEX *FASPRO*™ administration. Delayed systemic administration-related reactions have occurred in less than 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension and tachycardia. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritis, chills, vomiting, nausea, and hypotension.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX *FASPRO*™. Consider administering corticosteroids and other medications after the administration of DARZALEX *FASPRO*™ depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Local Reactions

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.6%. The most frequent (>1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 7 minutes (range: 0 minutes to 4.7 days) after starting administration of DARZALEX *FASPRO*™. Monitor for local reactions and consider symptomatic management.

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX *FASPRO*™ until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO*™, higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia

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

Embryo-Fetal Toxicity

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

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

Interference with Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX *FASPRO*™. Type and screen patients prior to starting DARZALEX *FASPRO*™.

Interference with Determination of Complete Response

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

ADVERSE REACTIONS

The most common adverse reaction (≥20%) with DARZALEX *FASPRO*™ monotherapy is: upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia.

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

Please see the full Prescribing Information for DARZALEX *FASPRO™*

DARZALEX® IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX® (daratumumab) is contraindicated in patients with a history of severe hypersensitivity (e.g., 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 see the full Prescribing Information for DARZALEX®

IMBRUVICA® IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage: Fatal bleeding events have occurred in patients who received 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) occurred in 4% of patients, with fatalities occurring in 0.4% of 2,838

patients who received IMBRUVICA® in 27 clinical trials. Bleeding events, including bruising and petechiae, occurred in 39% of patients who received IMBRUVICA®.

The mechanism for the bleeding events is not well understood.

Use of either anticoagulant or antiplatelet agents concomitantly with IMBRUVICA® increases the risk of major hemorrhage. Across clinical trials, 3.1% of 2,838 patients who received IMBRUVICA® without antiplatelet or anticoagulant therapy experienced major hemorrhage. The addition of antiplatelet therapy with or without anticoagulant therapy increased this percentage to 4.4%, and the addition of anticoagulant therapy with or without antiplatelet therapy increased this percentage to 6.1%. Consider the risks and benefits of anticoagulant or antiplatelet therapy when co-administered with IMBRUVICA®. Monitor for signs and symptoms of bleeding.

Consider the benefit-risk of withholding IMBRUVICA® for at least 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections: Fatal and non-fatal infections (including bacterial, viral, or fungal) have occurred with IMBRUVICA® therapy. Grade 3 or greater infections occurred in 21% of 1,476 patients who received IMBRUVICA® in clinical trials. Cases of progressive multifocal leukoencephalopathy (PML) and Pneumocystis jirovecii pneumonia (PJP) have occurred in patients treated with IMBRUVICA®. Consider prophylaxis according to standard of care in patients who are at increased risk for opportunistic infections.

Monitor and evaluate patients for fever and infections and treat appropriately.

Cytopenias: In 645 patients with B-cell malignancies who received IMBRUVICA® as a single agent, Grade 3 or 4 neutropenia occurred in 23% of patients, Grade 3 or 4 thrombocytopenia in 8% and Grade 3 or 4 anemia in 3%, based on laboratory measurements.

Monitor complete blood counts monthly.

Cardiac Arrhythmias: Fatal and serious cardiac arrhythmias have occurred with IMBRUVICA®. Grade 3 or greater ventricular tachyarrhythmias occurred in 0.2% of patients and Grade 3 or greater atrial fibrillation and atrial flutter occurred in 4% of 1,476 patients who received IMBRUVICA® in clinical trials. These events have occurred particularly in patients with cardiac risk factors, hypertension, acute infections, and a previous history of cardiac arrhythmias.

Periodically monitor patients clinically for cardiac arrhythmias. Obtain an ECG for patients who develop arrhythmic symptoms (e.g., palpitations, lightheadedness, syncope, chest pain) or new onset dyspnea. Manage cardiac arrhythmias appropriately, and if it persists, consider the risks and benefits of IMBRUVICA® treatment and follow dose modification guidelines.

Hypertension: Hypertension occurred in 19% of 1,476 patients who received IMBRUVICA® in clinical trials. Grade 3 or greater hypertension occurred in 8% of patients. Based on data from 1,124 of these patients, the median time to onset was 5.9 months (range, 0.03 to 24 months).

Monitor blood pressure in patients treated with IMBRUVICA® and initiate or adjust anti-hypertensive medication throughout treatment with IMBRUVICA® as appropriate.

Second Primary Malignancies: Other malignancies (10%), including non-skin carcinomas (4%), occurred among the 1,476 patients who received IMBRUVICA® in clinical trials. The most frequent second primary malignancy was non-melanoma skin cancer (6%).

Tumor Lysis Syndrome: Tumor lysis syndrome has been infrequently reported with IMBRUVICA®. Assess the baseline risk (e.g., high tumor burden) and take appropriate precautions.

Monitor patients closely and treat as appropriate.

Embryo-Fetal Toxicity: Based on findings in animals, IMBRUVICA® can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMBRUVICA® and for 1 month after the last dose. Advise males with female partners of reproductive potential to use effective contraception during the same time period.

ADVERSE REACTIONS

B-cell malignancies: The most common adverse reactions (≥30%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were thrombocytopenia (54.5%)*, diarrhea (43.8%), fatigue (39.1%), musculoskeletal pain (38.8%), neutropenia (38.6%)*, rash (35.8%), anemia (35.0%)*, and bruising (32.0%).

The most common Grade ≥ 3 adverse reactions (≥5%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia (20.7%)*, thrombocytopenia (13.6%)*, pneumonia (8.2%), and hypertension (8.0%).

Approximately 9% (CLL/SLL), 14% (MCL), 14% (WM) and 10% (MZL) of patients had a dose reduction due to adverse reactions. Approximately 4-10% (CLL/SLL), 9% (MCL), and 7% (WM [5%] and MZL [13%]) of patients discontinued due to adverse reactions.

cGVHD: The most common adverse reactions (≥20%) in patients with cGVHD were fatigue (57%), bruising (40%), diarrhea (36%), thrombocytopenia (33%)*, muscle spasms (29%), stomatitis (29%), nausea (26%), hemorrhage (26%), anemia (24%)*, and pneumonia (21%).

The most common Grade 3 or higher adverse reactions (≥5%) reported in patients with cGVHD were pneumonia (14%), fatigue (12%), diarrhea (10%), neutropenia (10%)*, sepsis (10%), hypokalemia (7%), headache (5%), musculoskeletal pain (5%), and pyrexia (5%).

Twenty-four percent of patients receiving IMBRUVICA® in the cGVHD trial discontinued treatment due to adverse reactions. Adverse reactions leading to dose reduction occurred in 26% of patients.

*Treatment-emergent decreases (all grades) were based on laboratory measurements.

DRUG INTERACTIONS

CYP3A Inhibitors: Co-administration of IMBRUVICA® with strong or moderate CYP3A inhibitors may increase ibrutinib plasma concentrations. Dose modifications of IMBRUVICA® may be recommended when used concomitantly with posaconazole, voriconazole, and moderate CYP3A inhibitors. Avoid concomitant use of other strong CYP3A inhibitors. Interrupt IMBRUVICA® if strong inhibitors are used short-term (e.g., for ≤ 7 days). See dose modification guidelines in USPI sections 2.4 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 recommended IMBRUVICA® dose and monitor more frequently for adverse reactions of IMBRUVICA®.

Please see the full Prescribing Information for IMBRUVICA®.

BALVERSA™ IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Ocular Disorders – BALVERSA® can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect. CSR/RPED was reported in 25% of patients treated with BALVERSA®, with a median time to first onset of 50 days. Grade 3 CSR/RPED, involving central field of vision, was reported in 3% of patients. CSR/RPED resolved in 13% of patients and was ongoing in 13% of patients at the study cutoff. CSR/RPED led to dose interruptions and reductions in 9% and 14% of patients, respectively, and 3% of patients discontinued BALVERSA®. Dry eye symptoms occurred in 28%

of patients during treatment with BALVERSA® and were Grade 3 in 6% of patients. All patients should receive dry eye prophylaxis with ocular demulcents as needed.

Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms. Ophthalmological examination should include assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography. Withhold BALVERSA® when CSR occurs and permanently discontinue if it does not resolve within 4 weeks or if Grade 4 in severity. For ocular adverse reactions, follow the dose modification guidelines *[see Dosage and Administration (2.3)]*.

Hyperphosphatemia – Increases in phosphate levels are a pharmacodynamic effect of BALVERSA® *[see Pharmacodynamics (12.2)].* Hyperphosphatemia was reported as adverse reaction in 76% of patients treated with BALVERSA®. The median onset time for any grade event of hyperphosphatemia was 20 days (range: 8–116) after initiating BALVERSA®. Thirty-two percent of patients received phosphate binders during treatment with BALVERSA®. Monitor for hyperphosphatemia and follow the dose modification guidelines when required *[see Dosage and Administration (2.2, 2.3)]*.

Embryo-fetal Toxicity – Based on the mechanism of action and findings in animal reproduction studies, BALVERSA® can cause fetal harm when administered to a pregnant woman. In a rat embryo-fetal toxicity study, erdafitinib was embryotoxic and teratogenic at exposures less than the human exposures at all doses studied. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose *[see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)]*.

Most common adverse reactions including laboratory abnormalities ≥20% :

Phosphate increased (76%), stomatitis (56%), fatigue (54%), creatinine increased (52%), diarrhea (47%), dry mouth (45%), onycholysis (41%), alanine aminotransferase increased (41%), alkaline phosphatase increased (41%), sodium decreased (40%), decreased appetite (38%), albumin decreased (37%), dysgeusia (37%), hemoglobin decreased (35%), dry skin (34%), aspartate aminotransferase increased (30%), magnesium decreased (30%), dry eye (28%), alopecia (26%), palmar-plantar erythrodysesthesia syndrome (26%), constipation (28%), phosphate decreased (24%), abdominal pain (23%), calcium increased (22%), nausea (21%), and musculoskeletal pain (20%). The most common Grade 3 or greater adverse reactions (>1%) were stomatitis (9%), nail dystrophy*, palmar-plantar erythrodysesthesia syndrome (6%), paronychia (3%), nail disorder*, keratitis†, onycholysis* (10%), and hyperphosphatemia.

*Included within onycholysis. †Included within dry eye.

- An adverse reaction with a fatal outcome in 1% of patients was acute myocardial infarction.
- Serious adverse reactions occurred in 41% of patients, including eye disorders (10%).
- Permanent discontinuation due to an adverse reaction occurred in 13% of patients. The most frequent reasons for permanent discontinuation included eye disorders (6%).
- Dosage interruptions occurred in 68% of patients. The most frequent adverse reactions requiring dosage interruption included hyperphosphatemia (24%), stomatitis (17%), eye disorders (17%), and palmar-plantar erythrodysesthesia syndrome (8%).
- Dose reductions occurred in 53% of patients. The most frequent adverse reactions for dose reductions included eye disorders (23%), stomatitis (15%), hyperphosphatemia (7%), palmar-plantar erythrodysesthesia syndrome (7%), paronychia (7%), and nail dystrophy (6%).

Drug Interactions

- Moderate CYP2C9 or strong CYP3A4 Inhibitors: Consider alternative agents or monitor closely for adverse reactions. (7.1)
- Strong CYP2C9 or CYP3A4 inducers: Avoid concomitant use with BALVERSA®. (7.1)
- Moderate CYP2C9 or CYP3A4 inducers: Increase BALVERSA® dose up to 9 mg. (7.1)
- Serum phosphate level-altering agents: Avoid concomitant use with agents that can alter serum phosphate levels before the initial dose modification period. (2.3, 7.1)
- CYP3A4 substrates: Avoid concomitant use with sensitive CYP3A4 substrates with narrow therapeutic indices. (7.2)
- OCT2 substrates: Consider alternative agents or consider reducing the dose of OCT2 substrates based on tolerability. (7.2)
- P-gp substrates: Separate BALVERSA® administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices. (7.2)

Use in Specific Populations

Lactation – Because of the potential for serious adverse reactions from erdafitinib in a breastfed child, advise lactating women not to breastfeed during treatment with BALVERSA® and for one month following the last dose.

Please see the full Prescribing Information for BALVERSA™

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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 ERLEADA® (apalutamide), DARZALEX® (daratumumab), IMBRUVICA® (ibrutinib), BALVERSA™ (erdafitinib), JNJ-4528, amivantamab, niraparib, teclistamab, cusatuzumab and lazertinib. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC or any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are

available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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