May 14, 2014

Janssen to Showcase Growing Body of Data at 2014 American Society of Clinical Oncology (ASCO) Annual Meeting

- **Research in hematological malignancies features: ibrutinib (IMBRUVICA®), siltuximab (SYLVANT™) and daratumumab; research in solid tumors features: abiraterone acetate (ZYTIGA®), ARN-509, trabectedin and JNJ-42756493**
- **" Note: This release corresponds to ASCO abstracts 7014, 7009, TPS8611^, TPS8615^, 8514, 8576, 8513, 8533, 5015^, 5025, 519, 520, 5086, 5058, 5061, 5026, TPS5100, TPS5612, 5551, 10561, 2501**

RARITAN, NJ, May 14, 2014 - Janssen Research & Development, LLC (Janssen) announced data related to seven compounds have been selected for presentation at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) being held May 30-June 3, 2014 in Chicago, IL. Abstracts have been accepted for presentation on hematological malignancies, prostate cancer and other solid tumors.

In hematology, these data feature ibrutinib, a therapy that targets and blocks a specific protein (Bruton's tyrosine kinase), which has shown to be important to cell functioning; siltuximab, an anti-interleukin-6 (IL-6) chimeric monoclonal antibody recently approved by the U.S. Food & Drug Administration (FDA); and daratumumab, an investigational human IgG1κ monoclonal antibody.

In prostate cancer and other solid tumors, these data feature abiraterone acetate, a CYP-17 inhibitor; ARN-509, an investigational androgen receptor antagonist; trabectedin, a synthetic alkaloid of marine origin; and JNJ-42756493, an investigational pan-fibroblast growth factor receptor (FGFR) inhibitor.

"Janssen has had a momentous year in oncology. Since last year's ASCO meeting, we have received approval from the U.S. FDA for two products-IMBRUVICA and SYLVANT-and we have also added ARN-509 to our pipeline," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "It's rewarding to see so many data on our approved and investigational compounds accepted for presentation at ASCO."

List of Company-Sponsored Research to Be Presented

Ibrutinib
Ibrutinib data will be featured in six studies selected for presentation and were sponsored by either Janssen or its collaboration partner, Pharmacyclics, Inc.:

- **Independent evaluation of ibrutinib efficacy 3 years post-initiation of monotherapy in patients with chronic lymphocytic leukemia/small lymphocytic leukemia including deletion 17p disease. (Abstract 7014)**
  Oral abstract session: Leukemia, Myelodysplasia, and Transplantation. Tuesday, June 3 at 11:33 a.m. CDT in E354a.
  Lead Author: Susan O'Brien, M.D., The University of Texas MD Anderson Cancer Center, Houston, TX, USA
- **A phase 1b/2 study evaluating activity and tolerability of the BTK inhibitor ibrutinib in combination with ofatumumab in patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and related diseases. (Abstract 7009)**
  Poster highlights session: Leukemia, Myelodysplasia, and Transplantation. Saturday, May 31 at 1:15 p.m. CDT in S405.
  Lead Author: Samantha Jaglowski, M.D., MPH, The Ohio State University Comprehensive Cancer Center, Columbus, OH, USA
- **A phase 3 study of ibrutinib in combination with either bendamustine and rituximab (BR) or rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) in patients with previously treated follicular lymphoma or marginal zone lymphoma. (Abstract TPS8611^)**
  General poster session: Lymphoma and Plasma Cell Disorders. Monday, June 2 at 1:15 p.m. CDT in S Hall A2.
  Lead Author: Nathan Fowler, M.D., The University of Texas MD Anderson Cancer Center, Houston, TX, USA
- **A randomized, double-blind, placebo-controlled phase 3 study of ibrutinib in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) in subjects with newly diagnosed nongerminal center B-cell subtype of diffuse large B-cell lymphoma (DLBCL). (Abstract TPS8615^)**
  General poster session: Lymphoma and Plasma Cell Disorders. Monday, June 2 at 1:15 p.m. CDT in S Hall A2.
  Lead Author: Anas Younes, M.D., Memorial Sloan Kettering Cancer Center, New York, NY, USA
- **Ibrutinib therapy for patients with relapsed or refractory mantle cell lymphoma: a budget impact analysis from a U.S. payer perspective. *(Publication only)***
  Electronic publication, available on www.asco.org
  Lead Author: Mekré Senbetta, Pharm.D., Janssen Scientific Affairs, LLC, Horsham, PA, USA

- **Patient-relevant symptoms and impacts of chronic lymphocytic leukemia: Evidence from online social networks-based qualitative research with treated and "watch and wait" patients. *(Publication only)***
  Electronic publication, available on www.asco.org
  Lead Author: Kelly McCarrier Ph.D., MPH, Health Research Associates, Inc., Seattle, WA, USA

Siltuximab
Two Janssen-sponsored abstracts for siltuximab have been accepted for presentation at ASCO:

- **Efficacy of siltuximab in patients with previously treated multicentric Castleman's disease (MCD). (Abstract 8514)**
  Oral abstract session: Myeloma. Monday, June 2 at 9:12 a.m. CDT in E354a.
  Lead Author: Frits van Rhee, M.D., Ph.D., University of Arkansas for Medical Sciences, Little Rock, AR, USA
- **Effect of siltuximab on lean body mass (LBM) in multicentric Castleman's disease (MCD) patients (pts). (Abstract 8576)**
  General poster session: Lymphoma and Plasma Cell Disorders. Monday, June 2 at 1:15 p.m. CDT in S Hall A2. Lead Author: Michael Sawyer, B.Sc.Phm., M.D., University of Alberta, Edmonton, Alberta, Canada

Daratumumab
Two daratumumab abstracts have been accepted for presentation and were jointly sponsored by Janssen and Genmab A/S. Janssen licensed daratumumab from Genmab A/S in 2012 and is working with the company to fully transition the development program to Janssen. The selected daratumumab abstracts at ASCO include:

- **Dose-dependent efficacy of daratumumab (DARA) as monotherapy in patients with relapsed or refractory multiple myeloma (RR MM). (Abstract 8513)**
  Oral abstract session: Myeloma. Monday, June 2 at 9 a.m. CDT in E354a.
  Lead Author: Henk Lokhorst, M.D., Ph.D., University Medical Center Utrecht, Utrecht, Netherlands
- **Safety and efficacy of daratumumab with lenalidomide and dexamethasone in relapsed or relapsed, refractory multiple myeloma. (Abstract 8533)**
  Poster highlights session: Lymphoma and Plasma Cell Disorders. Friday, May 30 at 1 p.m. CDT in S405.
  Lead Author: Torben Plesner, M.D., Vejle Hospital, Vejle, Denmark

Abiraterone Acetate
Abiraterone acetate data will be included in 13 company-sponsored abstracts at ASCO:

- **Association of serum (SR) and tissue (TX) abiraterone (ABI) levels with intraprostatic steroids and pathologic outcomes in men with high-risk localized prostate cancer (PCa). (Abstract 5015^)**
  Poster highlights session: Genitourinary (Prostate) Cancer. Saturday, May 31 at 1:15 p.m. CDT in E354b.
  Lead Author: Elahe Mostaghel, M.D., Ph.D., Fred Hutchinson Cancer Research Center, Seattle, WA, USA
- **Phase 1b study of abiraterone acetate (AA) and docetaxel (D) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC). (Abstract 5025)**
  Poster highlights session: Genitourinary (Prostate) Cancer. Saturday, May 31 at 1:15 p.m. CDT in E354b.
  Lead Author: Scott Tagawa, M.D., Weill Cornell Medical College, New York, NY, USA
- **Randomized phase 2 study of abiraterone acetate (AA) with or without exemestane (E) in postmenopausal patients (pts) with estrogen receptor-positive (ER+) metastatic breast cancer (MBC). (Abstract 519)**
  Poster highlights session: Breast Cancer - HER2/ER. Sunday, June 1 at 8 a.m. CDT in E354b.
  Lead Author: Joyce O'Shaughnessy, M.D., Texas Oncology-Baylor Charles A. Sammons Cancer Center, Dallas, TX, USA
- **Evaluation of biomarker association with efficacy for abiraterone acetate (AA) plus prednisone (P) with or without exemestane (E) in postmenopausal patients (pts) with estrogen receptor-positive (ER+) metastatic breast cancer (mBCa) progressing after a nonsteroidal aromatase inhibitor (NSAI). (Abstract 520)**
  Poster highlights session: Breast Cancer - HER2/ER. Sunday, June 1 at 8 a.m. CDT in E354b.
  Lead Author: Weimin Li, Ph.D., Janssen Research & Development, LLC, Spring House, PA, USA
- **Effect of abiraterone acetate and low-dose prednisone on PSA in patients with nonmetastatic castration-resistant prostate cancer: the results from IMAAGEN core study. (Abstract 5086)**
  General poster session: Genitourinary (Prostate) Cancer. Monday, June 2 at 1:15 p.m. CDT in S Hall A2.
  Lead Author: Charles Ryan, M.D., University of California-San Francisco, San Francisco, CA, USA
- **Predicting response to abiraterone acetate (AA): mRNA biomarker analysis of study COU-AA-302. (Abstract 5058)**
  General poster session: Genitourinary (Prostate) Cancer. Monday, June 2 at 1:15 p.m. CDT in S Hall A2.
  Lead Author: Deborah Ricci, Ph.D., Janssen Research & Development, LLC, Raritan, NJ, USA
- **Final analysis of a large, open-label global early access protocol (EAP) with abiraterone acetate (AA) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) progressing after chemotherapy. (Abstract 5061)**
  General poster session: Genitourinary (Prostate) Cancer. Monday, June 2 at 1:15 p.m. CDT in S Hall A2.
  Lead Author: Cora Sternberg, M.D., FACP, San Camillo and Forlanini Hospitals, Rome, Italy
- **Effect of concomitant medication use on outcomes of treatment and placebo arms of the COU-AA-301 and**

COU-AA-302 studies of abiraterone acetate in metastatic castration-resistant prostate cancer. *(Publication only)*
Electronic publication, available on www.asco.org
Lead Author: Robert Hamilton, M.D., University of Toronto, Toronto, Canada

- **Development and analysis of androgen receptor axis biomarkers of circulating tumor cells in Japanese metastatic castration-resistant prostate cancer patients treated with abiraterone acetate. *(Publication only)***
Electronic publication, available on www.asco.org
Lead Author: Weimin Li, Janssen Research & Development, LLC, Spring House, PA, USA
- **Treatment evolution for metastatic castration-resistant prostate cancer with recent introduction of new oral agents: retrospective analysis of real world data. *(Publication only)***
Electronic publication, available on www.asco.org
Lead Author: Thomas Flaig, M.D., University of Colorado Cancer Center, Aurora, CO, USA
- **Patient age and treatment sequencing in patients with prostate cancer: results of a multicenter observational study. *(Publication only)***
Electronic publication, available on www.asco.org
Lead Author: Jennifer Reichert, RainTree Oncology Services Corporation, San Diego CA, USA
- **Examining experiences of patients currently being treated with abiraterone acetate (AA) for metastatic castration resistant prostate cancer (mCRPC). *(Publication only)***
Electronic publication, available on www.asco.org
Lead Author: Ahmad Naim, M.D., Janssen Scientific Affairs, LLC, Horsham, PA, USA
- **Adherence patterns for abiraterone acetate and concomitant prednisone use in patients with prostate cancer. *(Publication only)***
Electronic publication, available on www.asco.org
Lead Author: Marie-Hélène Lafeuille, Groupe d'Analyse, Ltée, Montreal, QC, Canada

ARN-509
Two company-sponsored ARN-509 abstracts have been accepted for presentation:

- **ARN-509 in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) with and without prior abiraterone acetate (AA) treatment. (Abstract 5026)**
Poster highlights session: Genitourinary (Prostate) Cancer. Saturday, May 31 at 1:15 p.m. CDT in E354b.
Lead Author: Dana Rathkopf, M.D., Memorial Sloan Kettering Cancer Center, New York, NY, USA
- **A randomized double-blind, comparative study of ARN-509 plus androgen deprivation therapy (ADT) versus ADT alone in nonmetastatic castration-resistant prostate cancer (M0-CRPC): the SPARTAN trial. (Abstract TPS5100)**
General poster session: Genitourinary (Prostate) Cancer. Monday, June 2 at 1:15 p.m. CDT in S Hall A2.
Lead Author: Matthew Smith, M.D., Ph.D., Massachusetts General Hospital Cancer Center, Boston, MA, USA

Trabectedin
Trabectedin Four trabectedin abstracts have been accepted for presentation and were sponsored by Janssen or PharmaMar:

- **A phase 3 study of trabectedin (T) plus pegylated liposomal doxorubicin (PLD) versus PLD for treatment of advanced?relapsed epithelial ovarian, primary peritoneal, or fallopian tube cancer. (Abstract TPS5612)**
General poster session: Gynecologic Cancer. Saturday, May 31 at 8 a.m. CDT in S Hall A2.
Lead Author: Robert Coleman, M.D., The University of Texas MD Anderson Cancer Center, Houston, TX, USA
- **Trabectedin plus pegylated liposomal doxorubicin (PLD) prior to subsequent platinum chemotherapy in patients with platinum-resistant (PR) recurrent ovarian cancer (ROC): results from OVA-301 follow-up. (Abstract 5551)**
General poster session: Gynecologic cancer. Saturday, May 31 at 8 a.m. CDT in S Hall A2.
Lead Author: Nicoletta Colombo, M.D., Ph.D., University of Milan-Bicocca, European Institute of Oncology, Milan, Italy
- **Radiologic signs of adipocytic maturation (AM) in dedifferentiated liposarcoma (ddLPS) patients (pts) treated with trabectedin (T): Correlation with disease control. (Abstract 10561)**
General poster session: Sarcoma. Monday, June 2 at 8 a.m. CDT in S Hall A2.
Lead Author: Sree Tirumani, M.D., Dana-Farber Cancer Institute, Boston, MA, USA
- **Effects of cytochrome P450 inducer and inhibitor coadministration on the pharmacokinetics of trabectedin in patients with advanced or metastatic solid tumor. *(Publication only)***
Electronic publication, available on www.asco.org
Lead Author: Jean-Pascal Machiels, M.D., Ph.D., Université Catholique de Louvain, Cliniques Universitaires Saint-Luc, Brussels, Belgium

JNJ-42756493
One Janssen-sponsored abstract on the FGFR inhibitor JNJ-42756493 was accepted for presentation:

- **Phase 1 study of JNJ-42756493, a pan-fibroblast growth factor receptor (FGFR) inhibitor, in patients with**

advanced solid tumors. (Abstract 2501)
Oral abstract session: Developmental Therapeutics - Clinical Pharmacology and Experimental Therapeutics. Saturday, May 31 at 1:27 p.m. CDT in E Hall D2.
Lead Author: Rastislav Bahleda, M.D., Gustave Roussy Institute, Villejuif, France

About IMBRUVICA® (ibrutinib)
IMBRUVICA was one of the first therapies to receive U.S. approval via the FDA's Breakthrough Therapy Designation and was approved under the FDA's Subpart H regulation.[1] IMBRUVICA is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy and the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.[2] These indications are both based on an overall response rate (ORR). An improvement in survival or disease-related symptoms has not been established.[2]

IMBRUVICA works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[2] 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.[2,3] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.

For more information, visit www.IMBRUVICA.com.

Additional Information about IMBRUVICA®

INDICATION - IMBRUVICA® is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy and the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. These indications are both based on an overall response rate (ORR). An improvement in survival or disease-related symptoms has not been established.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
Hemorrhage - Five percent of patients with MCL and 6% of patients with CLL had Grade 3 or higher bleeding events (subdural hematoma, ecchymoses, gastrointestinal bleeding, and hematuria). Overall, bleeding events including bruising of any grade occurred in 48% of patients with MCL treated with 560 mg daily and 63% of patients with CLL treated at 420 mg daily.

The mechanism for the bleeding events is not well understood. IMBRUVICA® may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies. 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 have occurred with IMBRUVICA® therapy. At least 25% of patients with MCL and 35% of patients with CLL had infections Grade 3 or greater NCI Common Terminology Criteria for Adverse Events (CTCAE). Monitor patients for fever and infections and evaluate promptly.

Myelosuppression - Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients with MCL and 35% of patients with CLL. These included neutropenia (29%), thrombocytopenia (17%) and anemia (9%) in patients with MCL and neutropenia (27%) and thrombocytopenia (10%) in patients with CLL. Monitor complete blood counts monthly.

Renal Toxicity - Fatal and serious cases of renal failure have occurred with IMBRUVICA® therapy. Treatment-emergent increases in creatinine levels up to 1.5 times the upper limit of normal occurred in 67% of patients with MCL and 23% of patients with CLL. Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 9% of patients with MCL and 4% of patients with CLL. Periodically monitor creatinine levels. Maintain hydration.

Second Primary Malignancies - Other malignancies have occurred in 5% of patients with MCL and 10% of patients with CLL who have been treated with IMBRUVICA®. Four percent of patients with MCL had skin cancers, and 1% had other carcinomas. Eight percent of patients with CLL had skin cancers and 2% had other carcinomas.

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®. 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.

ADVERSE REACTIONS
CLL: The most commonly occurring adverse reactions (? 20%) in the clinical trial were thrombocytopenia*, diarrhea (63%), bruising (54%), neutropenia*, anemia*, upper respiratory tract infection (48%), fatigue (31%), musculoskeletal pain (27%), rash (27%), pyrexia (25%), constipation (23%), peripheral edema (23%), arthralgia (23%), nausea (21%), stomatitis (21%), sinusitis

(21%), and dizziness (21%).

*Treatment-emergent decreases (all grades) of platelets (71%), neutrophils (54%) and hemoglobin (44%) were based on laboratory measurements per IWCLL criteria and adverse reactions.

The most common Grade 3 or 4 non-hematological adverse reactions (? 5%) were pneumonia (8%), hypertension (8%), atrial fibrillation (6.3%), sinusitis (6%), skin infection (6%), dehydration (6.4%), and musculoskeletal pain (6%). Treatment-emergent Grade 3 or 4 cytopenias were reported in 35% of patients.

Five patients (10%) discontinued treatment due to adverse reactions in the trial (N=48). These included 3 patients (6%) with infections and 2 patients (4%) with subdural hematomas. Adverse reactions leading to dose reduction occurred in 13% of patients.

MCL: The most commonly occurring adverse reactions (? 20%) in the clinical trial were thrombocytopenia*, diarrhea (51%), neutropenia*, anemia*, fatigue (41%), musculoskeletal pain (37%), peripheral edema (35%), upper respiratory tract infection (34%), nausea (31%), bruising (30%), dyspnea (27%), constipation (25%), rash (25%), abdominal pain (24%), vomiting (23%), and decreased appetite (21%).

*Treatment-emergent decreases (all grades) of platelets (57%), neutrophils (47%) and hemoglobin (41%) were based on laboratory measurements and adverse reactions.

The most common Grade 3 or 4 non-hematological adverse reactions (? 5%) were pneumonia (7%), abdominal pain (5%), atrial fibrillation (5.4%), diarrhea (5%), fatigue (5%), and skin infections (5%). Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients.

Ten patients (9%) discontinued treatment due to adverse reactions in the trial (N=111).

The most frequent adverse reaction leading to treatment discontinuation was subdural hematoma (1.8%). Adverse reactions leading to dose reduction occurred in 14% of patients.

DRUG INTERACTIONS
CYP3A Inhibitors - Avoid concomitant administration with strong or moderate inhibitors of CYP3A. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA® dose.

CYP3A Inducers - Avoid co-administration with strong CYP3A inducers.
SPECIAL POPULATIONS - Hepatic Impairment - Avoid use in patients with baseline hepatic impairment.

For the full prescribing information, visit http://www.IMBRUVICA.com/.

SYLVANT is an anti-interleukin-6 (IL-6) chimeric monoclonal antibody that binds to human IL-6.[4] IL-6 is a multifunctional cytokine produced by various cells such as T cells, B cells, monocytes, fibroblasts and endothelial cells. Dysregulated overproduction of IL-6 from activated B cells in affected lymph nodes has been implicated in the pathogenesis of, or mechanism causing, MCD.[5] Information about ongoing studies with siltuximab can be found at www.clinicaltrials.gov.

On April 23, 2014, the U.S. FDA approved SYLVANT for the treatment of patients with MCD who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. SYLVANT was not studied in patients with MCD who are HIV positive or HHV-8 positive because SYLVANT did not bind to virally produced IL-6 in a nonclinical study.

On September 3, 2013, Janssen announced simultaneous submissions of a Biologic License Application (BLA) to the U.S. FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for siltuximab for the treatment of patients with MCD who are HIV negative and HHV-8 negative. The EMA has granted Accelerated Assessment of the MAA. On March 21 2014, the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending the marketing authorization of siltuximab for the treatment of adult patients with MCD who are HIV negative and human herpesvirus-8 (HHV-8) negative. Siltuximab has been granted orphan drug status in MCD in the U.S. and European Union.

Additional Information about SYLVANT™

INDICATION - SYLVANT™ (siltuximab) is indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-?8 (HHV-8) negative.

Limitation of Use. SYLVANT™ was not studied in patients with MCD who are HIV positive or HHV8 positive because SYLVANT™ did not bind to virally produced IL-6 in a nonclinical study.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS - Severe hypersensitivity reaction to siltuximab or any of the excipients in SYLVANT™.

Concurrent Active Severe Infections - Do not administer to patients with severe infections until the infection resolves. SYLVANT™ may mask signs and symptoms of acute inflammation including suppression of fever and of acute phase reactant such as C-reactive protein (CRP). Monitor patients closely for infections. Institute prompt anti-?infective therapy and do not administer further SYLVANT™ until the infection resolves.

Vaccinations - Do not administer live vaccines to patients receiving SYLVANT™ because interleukin-6 (IL-6) inhibition may interfere with the normal immune response to new antigens.

Infusion Related Reactions and Hypersensitivity - Stop the infusion if the patient develops signs of anaphylaxis. Discontinue further therapy.

Stop the infusion if the patient develops mild to moderate infusion reactions. If the reaction resolves, the infusion may be restarted at a lower infusion rate. Consider medicating with antihistamines, acetaminophen, and corticosteroids. Discontinue SYLVANT™ if the patient does not tolerate the infusion following these interventions. [see Adverse Reactions (6)].

Administer SYLVANT™ in a setting that provides resuscitation equipment, medication, and personnel trained to provide resuscitation.

Gastrointestinal (GI) Perforation - Use with caution in patients who may be at increased risk for GI perforation. Promptly evaluate patients presenting with symptoms that may be associated with or suggestive of GI perforation.

Adverse Reactions - The most common adverse reactions (>10% compared to placebo) in the MCD clinical trial were pruritus, increased weight, rash, hyperuricemia, and upper respiratory tract infection.

Drug Interactions - Cytochrome P450 (CYP450) Substrates - Upon initiation or discontinuation of SYLVANT™, in patients being treated with CYP450 substrates with narrow therapeutic index, perform therapeutic monitoring of effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) as needed and adjust dose. Exercise caution when SYLVANT™ is co-administered with CYP3A4 substrate drugs where a decrease in effectiveness would be undesirable (e.g., oral contraceptives, lovastatin, atorvastatin).

For more information on SYLVANT™, including the full prescribing information, visit www.SYLVANT.com.

About Daratumumab
In August 2012, Genmab A/S granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab. Daratumumab is an investigational human IgG1 monoclonal antibody (mAb) that binds with high affinity to CD38 on surface of multiple myeloma cells and induces rapid tumor cell death through diverse mechanisms of action. Daratumumab is in Phase 3 clinical development for multiple myeloma, and may also have potential in other malignant and pre-malignant diseases on which CD38 is expressed. In May 2013, daratumumab was granted Breakthrough Therapy Designation by the FDA for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and IMiD.

About ZYTIGA® (abiraterone acetate)
Since its first approval in the U.S. in 2011, ZYTIGA has been approved in more than 85 countries. More than 100,000 men worldwide have received treatment with it, and it is quickly becoming one of the cornerstones of treatment for metastatic castration-resistant prostate cancer (mCRPC).

More information about ZYTIGA, visit www.ZYTIGA.com.

Additional Information about ZYTIGA®

INDICATION - ZYTIGA® (abiraterone acetate) in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

IMPORTANT SAFETY INFORMATION

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

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

Adrenocortical Insufficiency (AI) - AI was reported in patients receiving ZYTIGA® in combination with prednisone/prednisolone, after an interruption of daily steroids and/or with concurrent infection or stress. Use caution and monitor for symptoms and signs of AI if prednisone/prednisolone is stopped or withdrawn, if prednisone/prednisolone 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 - Monitor liver function and modify, withhold, or discontinue ZYTIGA® dosing as recommended (see Prescribing Information for more information). Measure serum transaminases [alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] and bilirubin levels prior to starting treatment with ZYTIGA®, every two weeks for the first three months of treatment, and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the upper limit of normal (ULN) or the bilirubin rises above three times the ULN, interrupt ZYTIGA® treatment and closely monitor liver function.

Increased ZYTIGA® Exposures with Food - ZYTIGA® must be taken on an empty stomach. No food should be eaten for at least two hours before the dose of ZYTIGA® is taken and for at least one hour after the dose of ZYTIGA® is taken. Abiraterone Cmax and AUC0-? (exposure) were increased up to 17- and 10-fold higher, respectively, when a single dose of abiraterone acetate was administered with a meal compared to a fasted state.

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

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

Drug Interactions - ZYTIGA® is an inhibitor of the hepatic drug-metabolizing enzyme CYP2D6. Avoid co-administration with CYP2D6 substrates that have a narrow therapeutic index. If an alternative cannot be used, exercise caution and consider a dose reduction of the CYP2D6 substrate. In vitro, ZYTIGA® inhibits CYP2C8. There are no clinical data on its use with drugs that are substrates of CYP2C8. Patients should be monitored closely for signs of toxicity related to the CYP2C8 substrate if used concomitantly with abiraterone acetate.

Based on in vitro data, ZYTIGA® is a substrate of CYP3A4. The effects of strong CYP3A4 inhibitors or inducers on the pharmacokinetics of abiraterone have not been evaluated, in vivo. Strong inhibitors and inducers of CYP3A4 should be avoided or used with caution during treatment with ZYTIGA®.

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

About ARN-509

ARN-509 is a second generation androgen receptor (AR) antagonist being studied for the treatment of castration resistant prostate cancer (CRPC). In June 2013, Johnson & Johnson acquired Aragon Pharmaceuticals, Inc., including its investigational compound ARN-509, which works by inhibiting androgen receptor nuclear translocation and binding to androgen response elements.[6]

About Trabectedin

Trabectedin is a synthetic alkaloid of marine origin under investigation in the U.S.[7] for the treatment of adult patients with advanced soft tissue sarcoma and ovarian cancer. Trabectedin is approved outside of the U.S. under the brand name YONDELIS®, including in Europe, Canada, South Korea and Russia. The compound binds to the minor groove of DNA, bending the helix to the major groove, triggering a cascade of events ultimately resulting in perturbation of the cell cycle.[8] PharmaMar is the Marketing Authorization Holder and markets YONDELIS in Europe and Japan and Janssen has the rights in

the U.S. and the rest of the world.[9]

About JNJ-42756493
JNJ-42756493 is an investigational orally bioavailable pan-fibroblast growth factor receptor (FGFR) inhibitor. FGFR is a receptor tyrosine kinase essential to tumor cell proliferation, differentiation and survival; and aberration leading to FGFR pathway activation can lead to oncogenesis.[10] JNJ-42756493 is currently being evaluated in Phase 1 clinical trials.[11] It was discovered in collaboration with Astex Pharmaceuticals.

About Janssen Research & Development, LLC
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit http://www.janssenrnd.com for more information.

Janssen in Oncology
In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; competition, including technological advances, new products and patents attained by competitors; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; economic factors, such as interest rate and currency exchange rate fluctuations; general industry conditions including trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description 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, 2013, including in Exhibit 99 thereto, and our subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

References:

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[1] The U.S. Food and Drug Administration. CFR - Code of Federal Regulations Title 21. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314&showFR=1&subpartNode=21:5.0.1.1.4.8. Accessed May 2014.

[2]IMBRUVICA Prescribing Information. February 2014.

[3]Genetics Home Reference. Isolated growth hormone deficiency. Available from: http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency. Accessed May 2014.

[4]SYLVANT Prescribing Information. April 2014.

[5]El-Osta HE, Kurzrock R. Castleman's disease: from basic mechanisms to molecular therapeutics. Oncologist. 2011;16(4):497-511.

[6]Rathkopf DE et al. Phase I Study of ARN-509, a Novel Antiandrogen, in the Treatment of Castration-Resistant Prostate Cancer. Journal of Clinical Oncology. 2013 Oct 1;31(28):3525-30. Available from: http://jco.ascopubs.org/content/early/2013/09/03/JCO.2013.50.1684. Accessed May 2014.

[7]D'Incalci M and Galmarini CM. A Review of Trabectedin (ET-743): A Unique Mechanism of Action. Molecular Cancer Therapeutics. August 2010. 9; 2157. Available from: http://mct.aacrjournals.org/content/9/8/2157.full.pdf+html. Accessed May 2014.

[8]European Medicines Agency (EMA). YONDELIS (trabectedin) Summary of Product Characteristics. 2009. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000773/WC500045832.pdf. Accessed May 2014.

[9]PharmaMar. YONDELIS. Available from: http://www.pharmamar.com/yondelis.aspx. Accessed May 2014.

[10]National Cancer Institute. Pan-FGFR tyrosine kinase inhibitor JNJ-42756493. Available from: http://www.cancer.gov/drugdictionary?cdrid=741845. Accessed May 2014.

[11]U.S. National Institutes of Health (NIH). Clinicaltrials.gov. A Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of JNJ-42756493 in Patients With Advanced or Refractory Solid Tumors or Lymphoma. Last updated April 2014. Available from: http://clinicaltrials.gov/ct2/show/NCT01962532. Accessed May 2014.

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

Investor Relations:
Stan Panasewicz
Phone: 1-732-524-2524

Louise Mehrotra
Phone: 1-732-524-6491

.U.S. Medical Inquiries:

(SYLVANT, daratumumab, ZYTIGA, ARN-509, trabectedin and JNJ-42756493): 1-800-526-7736

(IMBRUVICA: Pharmacyclics):
1-877-877-3536