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 14 Abstracts in Prostate and Urothelial Cancers at ASCO GU 2018, Including New Data on Apalutamide (ARN-509), ZYTIGA® (abiraterone acetate) and Erdafitinib

- *Phase 3 SPARTAN clinical trial results for apalutamide in non-metastatic castration-resistant prostate cancer selected for Prostate Cancer Oral Abstract Session*
- *10 poster presentations for ZYTIGA® (abiraterone acetate) including new analyses from the Phase 3 LATITUDE clinical trial assessing ZYTIGA® plus prednisone and androgen deprivation therapy (ADT) in metastatic castration-naïve and metastatic hormone-sensitive prostate cancers*
- *Phase 2 erdafitinib data in patients with metastatic or unresectable urothelial carcinoma and FGFR alterations selected for Urothelial Cancers Rapid Fire Abstract Session*

RARITAN, NJ, January 25, 2018 – New data from the Janssen Pharmaceutical Companies of Johnson & Johnson will be presented at the American Society of Clinical Oncology Genitourinary (ASCO GU) 2018 Cancers Symposium taking place February 8-10 in San Francisco. In total, 14 company-sponsored abstracts with data for both investigational and approved compounds have been accepted for presentation, including for apalutamide and ZYTIGA® (abiraterone acetate) in prostate cancer, and for erdafitinib in urothelial cancer. Most notably, Phase 3 data results from the SPARTAN clinical trial, assessing apalutamide in non-metastatic castration-resistant prostate cancer, will be featured as part of the Prostate Cancer Oral Abstract Session on Thursday, February 8.

"New data featuring approved and investigational compounds continue to demonstrate our commitment to developing novel agents in areas of significant unmet medical need," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors at Janssen Research & Development, LLC. "We are especially excited to present results from the pivotal SPARTAN clinical trial with apalutamide in men with non-metastatic castration-resistant prostate cancer during this important oncology meeting."

Key company-sponsored data presentations include:

Apalutamide:

- SPARTAN, a phase 3 double-blind, randomized study of apalutamide (APA) vs placebo (PBO) in patients (pts) with nonmetastatic castration-resistant prostate cancer (nmCRPC) (Abstract #161)
    - These data will be presented in Oral Abstract Presentation during Session A of the Prostate Cancer Program from 1:00 pm – 2:30 pm PST on Thursday, February 8th

ZYTIGA®:

- Abiraterone acetate (AA) plus prednisone (P) 5 mg QD in metastatic castration-naïve prostate cancer (mCNPC): Detailed safety analyses from the LATITUDE phase 3 trial (Abstract #182)
    - These data will be presented in Poster Presentation Session A from 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST on Thursday, February 8th
- Medical resource utilization (MRU) of abiraterone acetate plus prednisone (AAP) added to androgen deprivation therapy (ADT) in metastatic castration-naive prostate cancer: Results from LATITUDE (Abstract #201)
    - These data will be presented in Poster Presentation Session A from 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST on Thursday, February 8th
- Efficacy and safety of abiraterone acetate (AA) and low-dose prednisone (P) in Japanese patients with newly diagnosed, metastatic, hormone-naïve prostate cancer (mHNPC); Subgroup analysis of LATITUDE trial (Abstract #286)
    - These data will be presented in Poster Session B from 12:15 pm – 1:45 pm and 6:00 pm – 7:00 pm PST on Friday, February 9th

Erdafitinib:

- Erdafitinib (ERDA; JNJ-42756493), a pan-fibroblast growth factor receptor (FGFR) inhibitor, in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFRa): phase 2 continuous versus intermittent dosing (Abstract #411)
    - These data will be presented in Rapid Fire Abstract Session during the Urothelial Carcinoma Program from 6:00 pm – 7:00 pm PST on Friday, February 9th

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

Abstract No.	**Title**	**Date/Time**
Apalutamide		
Abstract #161	SPARTAN, a phase 3 double-blind, randomized study of apalutamide (APA) vs placebo (PBO) in patients (pts) with nonmetastatic castration-resistant prostate cancer (nmCRPC)	Oral Abstract Session A Thursday, February 8th 1:00 pm – 2:30 pm PST
Abstract #27	Association of prostate-specific antigen (PSA) trajectories with risk for metastasis and mortality in non-metastatic castration-resistant prostate cancer (nmCRPC)	Poster Session A Thursday, February 8th 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST
ZYTIGA®		
Abstract #182	Abiraterone acetate (AA) plus prednisone (P) 5 mg QD in metastatic castration-naïve prostate cancer (mCNPC): Detailed safety analyses from the LATITUDE phase 3 trial	Poster Session A Thursday, February 8th 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST
Abstract #201	Medical resource utilization (MRU) of abiraterone acetate plus prednisone (AAP) added to androgen deprivation therapy (ADT) in metastatic castration-naive prostate cancer: Results from LATITUDE	Poster Session A Thursday, February 8th 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST
Abstract #196	Real-world evidence in patient-related outcomes (PROs) of metastatic castrate-resistant prostate cancer (mCRPC) patients treated with abiraterone acetate plus prednisone (AA+P)	Poster Session A Thursday, February 8th 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST
Abstract #200	Indirect treatment comparison (ITC) of abiraterone acetate (AA) plus prednisone (P) and docetaxel (DOC) on patient-reported outcomes (PROs) in metastatic castration-naïve prostate cancer (mCNPC)	Poster Session A Thursday, February 8th 11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST
Abstract #217	Neuropsychiatric adverse events of abiraterone acetate and enzalutamide:	Poster Session A Thursday, February 8th

	meta-analysis of randomized clinical trials with real world reporting patterns from EudraVigilance	11:30 am – 1:00 pm and 5:15 pm – 6:15 pm PST
Abstract #286	Efficacy and safety of abiraterone acetate (AA) and low-dose prednisone (p) in Japanese patients with newly diagnosed, metastatic, hormone-naïve prostate cancer (mHNPC); Subgroup analysis of LATITUDE Trial	Poster Session B Friday, February 9th 12:15 pm – 1:45 pm and 6:00 pm – 7:15 pm PST
Abstract #296	Real-world study of enzalutamide and abiraterone acetate (with prednisone) tolerability (REAAcT) - results	Poster Session B Friday, February 9th 12:15 pm – 1:45 pm and 6:00 pm – 7:15 pm PST
Abstract #320	Real world patterns of treatment sequencing in Canada for metastatic castrate-resistant prostate cancer	Poster Session B Friday, February 9th 12:15 pm – 1:45 pm and 6:00 pm – 7:15 pm PST
Abstract #321	Patterns of prostate cancer management across Canadian prostate cancer treatment specialists	Poster Session B Friday, February 9th 12:15 pm – 1:45 pm and 6:00 pm – 7:15 pm PST
Abstract #343	Evolution of neuropsychiatric adverse events of abiraterone acetate and enzalutamide treatments reported in EudraVigilance, in metastatic castration resistant prostate cancer patients	Poster Session B Friday, February 9th 12:15 pm – 1:45 pm and 6:00 pm – 7:15 pm PST
Erdafitinib		
Abstract #411	Erdafitinib (ERDA; JNJ-42756493), a pan-fibroblast growth factor receptor (FGFR) inhibitor, in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFRa): Phase 2 continuous versus intermittent dosing	Rapid Fire Abstract Session (Oral Abstract Presentation) Friday, February 9th 6:00 pm – 7:00 pm PST
Abstract #450	Efficacy of programmed death 1 (PD-1) and programmed death 1 ligand (PD-L1) inhibitors in patients with FGFR mutations and gene fusions: Results from a data analysis of an ongoing phase 2 study of erdafitinib (JNJ-42756493) in patients (pts) with advanced urothelial cancer (UC)	Poster Session B Friday, February 9th 12:15 pm – 1:45 pm and 6:00 pm – 7:15 pm PST

About ZYTIGA®

ZYTIGA® (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). ZYTIGA® blocks CYP17-mediated androgen production, which fuels prostate cancer growth, at three sources: in the testes, adrenals and the prostate tumor tissue.

Since its first approval in the U.S. in 2011, ZYTIGA® has been approved in combination with prednisone/prednisolone in 105 countries. More than 330,000 men worldwide, including 113,000 in the U.S., have received treatment with it, and it was the number one prescribed oral medication in the U.S. for men with mCRPC in 2016.

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

Important Safety Information - ZYTIGA®

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

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

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

Hepatotoxicity - In post-marketing experience, there have been ZYTIGA®-associated

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

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

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

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

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

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

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

About Apalutamide (ARN-509)

Apalutamide is an investigational, next-generation oral androgen receptor inhibitor that blocks the androgen signaling pathway in prostate cancer cells, and prevents binding of androgen to the androgen receptor and translocation of the androgen receptor to the nucleus of the cancer cell.

About Erdafitinib

Erdafitinib is a pan-fibroblast Growth Factor Receptor (FGFR) tyrosine kinase inhibitor currently being evaluated by Janssen in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer. Additional research is also being conducted to explore the use of erdafitinib in other cancer indications.

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 continued study and development of ZYTIGA® (abiraterone acetate), apalutamide, and erdafitinib. 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, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products or new indications; manufacturing difficulties or delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns of purchasers of health care products and services; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

# # #