News Release

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Janssen to Present Robust Evidence for Solid Tumor Portfolio and Pipeline at 2021 ASCO GU

Multiple data presentations to show long-term benefit and consistency of ERLEADA® (apalutamide)▼ in advanced prostate cancer; oral presentations to highlight Phase 3 ACIS, TITAN and SPARTAN study results

BEERSE, BELGIUM February 3, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today it will highlight the depth of its solid tumor portfolio at the American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium with 12 data presentations, including three company-sponsored oral presentations from the apalutamide clinical development program. The virtual meeting will take place 11-13 February.

"Janssen's extensive data presentations at ASCO GU are testament of our commitment to clinical research in genitourinary cancers -- to deliver innovative therapies that improve patient outcomes and address critical unmet needs," said Dr

Joaquín Casariego, M.D., Therapeutic Area Lead Oncology for Europe, Middle East & Africa, Janssen-Cilag S.A. "The latest research from the TITAN Phase 3 trial and our prostate cancer portfolio improves clinical understanding and opens new treatment pathways for a broader group of patients."

New Analyses for Apalutamide Phase 3 Studies Highlight Breadth of Ongoing Clinical Development Program

Data from three Phase 3 registrational clinical trials will be featured in oral presentations:

- **ACIS**: Analysis evaluating apalutamide in combination with abiraterone acetate plus prednisone versus abiraterone acetate plus prednisone in patients with chemo-naïve metastatic castration-resistant prostate cancer (Abstract #9)[1]
- **TITAN**: Final analysis with close to four years of follow-up data evaluating apalutamide versus placebo on overall survival (OS) and other endpoints in patients with metastatic hormone-sensitive prostate cancer (mHSPC) receiving hormone therapy (Abstract #11)[2]
- **SPARTAN**: Post-hoc analysis data from a biomarker cohort study identifying the molecular signatures associated with long-term response to apalutamide (Abstract #8)[3]

Combined, the apalutamide focused presentations include data from more than 2,000 patients across multiple studies. Apalutamide has shown a statistically significant improvement in OS in its approved indications of metastatic hormone-sensitive prostate cancer (TITAN) and non-metastatic castration-resistant prostate cancer (SPARTAN).[4] Both TITAN and SPARTAN trials confirm the safety of apalutamide, with over four years of patient follow-up demonstrating exposure-adjusted rates of Grade 3 and 4 adverse events for apalutamide that are comparable to androgen deprivation therapy alone.[5]

Further details about these data and the science that Janssen is advancing for patients with genitourinary cancers will be made available at ASCO GU via the

Janssen media event, *Prioritising Prostate Cancer* (February 12th, 2021 at 16:30 CET).

Abstracts to be presented at the meeting include:

Abstract No.	**Title**	**Date/Time**
Apalutamide		
	Oral Presentations	
Abstract #8	Molecular Determinants Associated with Long-Term Response to Apalutamide in Non-Metastatic Castration-Resistant Prostate Cancer	Thursday, February 11 6:45 PM – 8:00 PM CET
Abstract #9	Results from ACIS, a Randomized, Placebo-Controlled Double-Blind Phase 3 Study of Apalutamide and Abiraterone Acetate Plus Prednisone (AAP) Versus AAP in Patients with Chemo-Naive Metastatic Castration-Resistant Prostate Cancer	Thursday, February 11 6:45 PM – 8:00 PM CET
Abstract #11	Final Analysis Results From TITAN: A Phase 3 Study of Apalutamide vs Placebo in Patients with Metastatic Castration-Sensitive Prostate Cancer Receiving Androgen Deprivation Therapy	Thursday, February 11 9:30 PM – 10:15 PM CET
	Poster Presentations	
Abstract #44	Medication Adherence Among Prostate Cancer Patients Using Advanced Oral Therapies	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #64	Health-Related Quality of Life Analysis from a Randomized Phase 2 Trial of Androgen Signaling Inhibitors with or without Androgen Deprivation Therapy for Castration-Sensitive Prostate Cancer: LACOG0415	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #83	Outcomes in Men with Metastatic Castrate-Resistant Prostate Cancer Treated with Early Platinum-Based Chemotherapy Following an Unsatisfactory Response to Androgen Receptor Inhibition as Part of the Phase 2 Dynamic Allocation Modular Sequential (DynAMo) Trial	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #90	Interim Analysis of STARTAR: A Phase 2 Salvage Trial of Androgen Receptor Inhibition with Androgen Deprivation Therapy and Apalutamide with Radiation Therapy Followed by Docetaxel in Men with PSA Recurrent	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting

	Prostate Cancer After Radical Prostatectomy	
Erdafitinib		
	Poster Presentation	
Abstract #426	Management of Fibroblast Growth Factor Receptor Inhibitor Treatment-Emergent Adverse Events of Interest in Patients with Locally Advanced or Metastatic Urothelial Carcinoma	Poster Session: Urothelial Carcinoma, available on-demand throughout the meeting
Niraparib		
	Poster Presentation	
Abstract #TPS176	AMPLITUDE: A Study of Niraparib in Combination with Abiraterone Acetate Plus Prednisone (AAP) Versus AAP for the Treatment of Patients with Deleterious Germline or Somatic Homologous Recombination Repair Gene-Altered Metastatic Castration-Sensitive Prostate Cancer	Trials in Progress Poster Session: Advanced Prostate Cancer, available on-demand throughout the meeting
Other		
	Poster Presentations	
Abstract #47	Real-World Utilization of Docetaxel Among Men with De Novo Metastatic Castration-Sensitive Prostate Cancer: A Population-Based Study in Men Aged 66 or Older	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #50	Geographic Variation in Systemic Therapy in Men Age 66 Years and Older With De Novo Metastatic Castration Sensitive Prostate Cancer: A Population-Based Study in a Single Payer Health-System	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #149	Prognostic Association Between Common Laboratory Tests and Overall Survival in Men with De Novo Metastatic Castration-Sensitive Prostate Cancer: A Population-Based Study	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting

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About apalutamide

Apalutamide is an orally administered, selective androgen receptor (AR) inhibitor approved in Europe and is indicated in

- adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease, and
- in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC), also known as metastatic castration-sensitive prostate cancer (mCSPC), in combination with androgen deprivation therapy (ADT).[4]

About abiraterone acetate

Abiraterone acetate, an orally administered androgen biosynthesis inhibitor, in combination with prednisone or prednisolone is approved in Europe for

- the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT);
- the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of ADT in whom chemotherapy is not yet clinically indicated, and
- the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen[6].

Additionally, abiraterone acetate was approved for the treatment of high-risk metastatic hormone-sensitive prostate cancer (mHSPC) by the U.S. FDA on February 8, 2018.[7,8] Since its first approval in Europe in 2011, abiraterone acetate has been approved in combination with prednisone or prednisolone, in more than 105 countries and has been prescribed to more than 700,000 patients worldwide.[8]

About erdafitinib

Erdafitinib is a once-daily, oral fibroblast growth factor receptor (FGFR) kinase inhibitor that is being studied in patients with selected FGFR gene alterations in locally advanced or metastatic urothelial cancer, in Bacillus Calmette-Guérin (BCG) experienced, high risk non-muscle-invasive bladder cancer and in advanced solid tumours.[9,10,11,12,13] In 2019 erdafitinib was approved in the U.S. for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) that has susceptible FGFR3 or FGFR2 genetic alterations and who have progressed during or following at least one line of prior platinum-containing chemotherapy, including

within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.[14] In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialise erdafitinib.[15]

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. Ongoing studies include the Phase 3 **AMPLITUDE** study evaluating niraparib in combination with abiraterone acetate plus prednisone in a biomarker-selected patient population with mHSPC;[16] the Phase 3 **MAGNITUDE** study evaluating niraparib in combination with abiraterone acetate plus prednisone in adults with mCRPC;[17] and **QUEST**, a Phase 1b/2 study of niraparib combination therapies for the treatment of mCRPC.[18]

In April 2016, Janssen entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (acquired by GSK in 2018), for exclusive rights to niraparib in prostate cancer.[19] In Europe, niraparib is indicated for the maintenance treatment of adult patients with advanced epithelial high-grade 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 platinum sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.[20]

About The Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen-Cilag, S.A., Janssen

Biotech, Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 apalutamide for the treatment of patients with non-metastatic castration-resistant prostate cancer, abiraterone acetate, erdafitinib and niraparib. 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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV and/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 behaviour 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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