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Janssen to Present Key Data from Across Its Expansive Oncology Portfolio at ESMO 2020 Virtual Congress

- *Safety and efficacy data from the Phase 1 CHRYSALIS study exploring amivantamab in combination with lazertinib in patients with advanced EGFR-mutated NSCLC*
- *Subgroup analysis of a Phase 2 study of erdafitinib in patients with metastatic or surgically unresectable urothelial cancers that harbor specific FGFR genomic alterations*
- *Health-Related Quality of Life data from the final analysis of the SPARTAN study of apalutamide in patients with nmCRPC*
- *Presentation of first in-human data for JNJ-9178 (PRMT5 inhibitor) in patients with advanced cancers*

BEERSE, BELGIUM, September 14, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced multiple data presentations from its oncology portfolio and pipeline, including key data in lung cancer and bladder cancer, will be featured as part of the European Society for Medical Oncology (ESMO) Virtual Congress 2020, Science Weekend taking place 19–21 September.

Thirteen abstracts featuring Janssen data have been selected for presentation during the virtual congress, including an oral presentation and live Q&A of the latest data from the Phase 1 dose escalation study investigating amivantamab (JNJ-61186372) in combination with lazertinib in patients with advanced EGFR-mutated non-small cell lung cancer (NSCLC); updates on multiple Phase 1/2 studies evaluating erdafitinib in the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC); an update on patient-reported outcomes on health-related quality of life data from the final analysis of the Phase 3 SPARTAN study of apalutamide in patients with non-metastatic castration resistant prostate cancer (nmCRPC) with over four years of follow up. The full final analysis of the SPARTAN study was also recently published in *European Urology*.[1] In addition, Janssen makes its first presentation of in-human data for early-stage investigational protein arginine methyltransferase 5 (PRMT5) inhibitor JNJ-9178 in multiple tumour models (relapsed/refractory B cell non-Hodgkin lymphoma or advanced solid tumours, including patients with lower risk myelodysplastic syndromes). [2,3]

"Janssen's data at this year's congress demonstrates our continued commitment to advancing our broad oncology portfolio, driven by the critical unmet needs in solid tumours for some of the most prevalent cancers in Europe," said Dr Joaquín Casariego, M.D., Janssen Therapeutic Area Lead, Oncology for Europe, Middle East & Africa, Janssen-Cilag S.A. "The advancement of new approaches to cancer treatment and interception at earlier stages of the disease is vital to improve clinical outcomes and ultimately enhancing the quality of life for those affected by an oncologic diagnosis."

Company-sponsored abstracts to be presented at the meeting include:

Abstract/Presentation No.	Title
Amivantamab	
Proffered Paper 1: NSCLC Metastatic **Sunday 20th September** **14:37–14:49 CET**	
Abstract #1258O	Amivantamab (JNJ-61186372), an EGFR-MET bispecific antibody, in combination with lazertinib, a 3rd-generation tyrosine kinase inhibitor (TKI), in advanced EGFR NSCLC
On-Demand E-Poster Display Session **Thursday 17th September**	
Abstract #1405P	Survival of patients with Non-Small Lung Cancer and Exon 20 insertion mutation from the Czech Republic
JNJ-9178	
On-Demand Mini Oral Session: Development Therapeutics **Friday 18th September**	
Abstract #537MO	First-in-Human Study of JNJ-64619178, a Protein Arginine Methyltransferase 5 (PRMT5) inhibitor, in Patients with Advanced Cancers
Erdafitinib	
On-Demand E-Poster Display Session **Thursday 17th September**	
Abstract #603TiP	Phase 2, Open-Label Study of Erdafitinib in Adult and Adolescent Patients with Advanced Solid Tumors Harboring Fibroblast Growth Factor Receptor (FGFR) Gene Alterations
Abstract #750P	Erdafitinib in Patients with Locally Advanced or Metastatic Urothelial Carcinoma (mUC): Subgroup Analyses of Long-Term Efficacy Outcomes of a Pivotal Phase 2 Trial (BLC2001)
Abstract #751P	Analysis of Circulating Tumor DNA (ctDNA) From the Phase 2 BLC2001 Trial of Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma (mUC) to Identify Markers of Intrinsic Resistance to Fibroblast Growth Factor Receptor (FGFR)-Targeted Therapy
Abstract #752P	Updated Data From the NORSE Trial of Erdafitinib Plus Cetrelimab in Patients with Metastatic or Locally Advanced Urothelial Carcinoma (mUC) and Specific Fibroblast Growth Factor Receptor (FGFR) Alterations
Abstract #757P	An Observational Study of Outcomes of Patients with Advanced Urothelial Carcinoma (UC) After Anti-programmed Death-(Ligand) 1 (PD-[L]1) Therapy by

	Fibroblast Growth Factor Receptor Gene Alteration (FGFRa) Status
Abstract #758P	Assessment of Prognostic and Predictive Value of FGFR Alterations (FGFRa) in a Real-World Cohort of Patients with High-Risk pT1 Non-Muscle-Invasive Bladder Cancer (NMIBC)
Apalutamide	
On-Demand E-Poster Display Session **Thursday 17th September**	
Abstract #632P	Health-Related Quality of Life (HRQoL) at Final Analysis of the SPARTAN Study of Apalutamide vs Placebo in Patients with Nonmetastatic Castration-Resistant Prostate Cancer (nmCRPC) Receiving Androgen Deprivation Therapy (ADT)
Abstract #630P	Apalutamide for Non-Metastatic Castration Resistant Prostate Cancer (nmCRPC): A Comparison of Real-Life Experience From an International Named Patient Program vs the Prior Phase 3 Clinical Study
Niraparib	
On-Demand E-Poster Display Session **Thursday 17th September**	
Abstract #689TiP	NRG Oncology's GU007 (NADIR) TiP: A Randomized Phase II Trial of Niraparib With Standard Combination Androgen Deprivation Therapy (ADT) and Radiotherapy in High-Risk Prostate Cancer (With Initial Phase I)
Big Data and Artificial Intelligence Research	
On-Demand E-Poster Display Session **Thursday 17th September**	
Abstract #695TiP	ORACULUM: A Retrospective Observational Epidemiological Study Using Artificial Intelligence and Natural Language Processing in Electronic Health Records to Characterize the Prostate Cancer pathway, Management and Outcomes in Europe, Middle East and Africa (EMEA region)

#END#

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] In the U.S. apalutamide is also indicated for the treatment of nmCRPC and mCSPC.[5]

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.[6,7,8,9,10,11] 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.[12] In 2008, Janssen Pharmaceutica N.V. entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialise erdafitinib.[13]

About amivantamab

Amivantamab (JNJ-6372) is an investigational EGFR-MET bispecific antibody with immune cell-directing activity, which targets activating and resistance EGFR mutations, and MET pathway activation.[14],[15] The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.[16]

About lazertinib

Lazertinib[i] is an oral, third-generation, selective inhibitor of certain forms of the epidermal growth factor receptor (EGFR) with activating mutations, including the resistance mutation T790M, exon 19 deletions (Del19), and the L858R mutation, with potential antineoplastic activity.[17] It is currently being explored in combination with amivantamab in patients with advanced non-small cell lung cancer.[18]

[i] In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.

About JNJ-9178

JNJ-64619178 is an oral, selective protein arginine methyltransferase 5 inhibitor which is currently being investigated in a Phase 1 study for the treatment of patients with relapsed/refractory B cell non-Hodgkin lymphoma or advanced solid tumours, including patients with lower risk myelodysplastic syndromes.[3,19]

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.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding potential benefits and further benefits of apalutamide, erdafitinib and amivantamab and JNJ-9178. 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 Research & Development, LLC, 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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