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Janssen to Present New Data in Urothelial, Haematologic and Prostate Cancers at ASCO 2018, including Best of ASCO Selections

- *Urothelial - Phase 2 data for investigational urothelial cancer therapy erdafitinib*
- *Haematologic - Imbruvica®▼(ibrutinib) Phase 3 data in first-line and relapsed/refractory Waldenström's macroglobulinemia; Darzalex®▼(daratumumab) Phase 1 combination data in relapsed/refractory multiple myeloma*
- *Prostate - Apalutamide Phase 3 data analyses evaluating new clinical trial endpoints in prostate cancer*

BEERSE, BELGIUM, 18 May, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson, today announced 21 company-sponsored abstracts will be presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL on June 1-5. New data analyses in support of a portfolio of products, including the investigational treatments erdafitinib and apalutamide, as well as approved treatments Imbruvica® (ibrutinib), Darzalex® (daratumumab), and Zytiga® (abiraterone acetate) will be highlighted across urothelial, haematologic and prostate cancers.

Notably, Phase 2 trial results for the investigational compound erdafitinib, which received U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation, will be presented during an oral presentation on Sunday, June 3 (Abstract #4503).[1,2] For haematologic cancers, Phase 3 data from the iNNOVATE study will provide the first look at ibrutinib plus rituximab versus placebo plus rituximab in patients with newly diagnosed and relapsed/refractory Waldenström's macroglobulinemia (WM) (Abstract #8003).[3] In addition, Phase 2 data from the CAPTIVATE study will be presented evaluating ibrutinib plus venetoclax in first-line chronic lymphocytic

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leukaemia (CLL) (Abstract #7502).[4] Oral presentations for erdafitinib and ibrutinib have been selected to be featured at the Best of ASCO 2018 Meetings, which highlight cutting-edge science and reflect the leading research in oncology.

"The breadth of new data from our portfolio shows our commitment to finding solutions for patients living with cancer according to their specific treatment needs," said Dr Ivo Winiger-Candolfi, Oncology Therapeutic Area Lead, Janssen Europe, Middle East and Africa. "It reinforces our dedication to work with our partners and move a step closer to making cancer a preventable, chronic or curable disease."

Selected data presentations include:

- **Erdafitinib:** Results from the primary analysis of the Phase 2 study of erdafitinib (ERDA; JNJ-42756493) in patients with metastatic or unresectable urothelial carcinoma (mUC) and Fibroblast Growth Factor Receptor alterations (FGFRalt).
    - These data will be featured in an oral presentation from 9:00 – 9:12 a.m. CDT on Sunday, June 3 (Abstract #4503)[1] and have been selected for the Best of ASCO 2018 Meetings.
- **Ibrutinib:** Findings from the Phase 3 placebo-controlled iNNOVATE study will be presented, assessing ibrutinib plus rituximab versus placebo plus rituximab in patients with newly diagnosed and relapsed/refractory WM.*
    - These data will be featured in an oral presentation from 3:45 – 3:57 p.m. CDT on Friday, June 1 (Abstract #8003)[3] and have been selected for the Best of ASCO 2018 Meetings.
- **Ibrutinib:** Early results from the Phase 2 CAPTIVATE study will be presented, evaluating ibrutinib in combination with venetoclax in first-line CLL.*
    - These data will be featured in an oral presentation from 10:09 – 10:21 a.m. CDT on Sunday, June 3 (Abstract #7502) and have been selected for the Best of ASCO 2018 Meetings.[4]
- **Daratumumab:** Phase 1 data from the MMY1001 study will report on the efficacy and safety of daratumumab in combination with carfilzomib and dexamethasone in lenalidomide-refractory patients with relapsed multiple myeloma.
    - These data will be presented in an oral presentation from 3:09 – 3:21 p.m. CDT on Friday, June 1 (Abstract #8002).[5]
- **Daratumumab:** Follow-up efficacy and safety data from the pivotal Phase 3 ALCYONE study will be presented for daratumumab in combination with bortezomib, melphalan and prednisone in patients with newly diagnosed multiple myeloma who are transplant ineligible.

  - These data will be presented in a poster presentation from 8:00 – 11:30 a.m. CDT on Monday, June 4 (Abstract #8031).[6]

- **Daratumumab:** Safety run-in results from the Phase 3 ANDROMEDA study will be presented evaluating the subcutaneous use of daratumumab in combination with cyclophosphamide, bortezomib, and dexamethasone in patients with newly diagnosed amyloid light chain (AL) amyloidosis.[7] Amyloidosis is an incurable disease in which cells that normally produce antibodies make an abnormal protein that deposits in and causes damage to organs such as the heart and kidneys.[8]
  - These data will be presented in a poster discussion presentation from 3:00 – 4:15 p.m. CDT on Monday, June 4 (Abstract #8011).

- **Apalutamide**: New analyses from the pivotal Phase 3 SPARTAN clinical trial will be presented examining the relationship between time to metastasis (TTM) and site of metastases in patients with non-metastatic castration-resistant prostate cancer (nmCRPC).
  - These data will be presented in a poster presentation from 1:15 – 4:45 p.m. CDT on Saturday, June 2 (Abstract #5033).[9]

- **Abiraterone acetate:** New findings from the pivotal Phase 3 LATITUDE clinical trial in patients with metastatic high-risk castration-sensitive prostate cancer (CSPC) will be presented.
  - These data will be presented in a poster presentation from 1:15 – 4:45 p.m. CDT on Saturday, June 2 (Abstract #5028).[10]
- **Prostate Cancer**: New analysis exploring the association between metastasis-free survival (MFS) and overall survival (OS) will be presented in nmCRPC for the first time.
  - These data will be presented in a poster presentation from 1:15 – 4:45 p.m. CDT on Saturday, June 2 (Abstract #5032).[11]

For more information on the abstracts presented by Janssen, please click here.

**Abstracts were submitted by ibrutinib co-developer partner, Pharmacyclics, an AbbVie company.*

#ENDS#

About erdafitinib

Erdafitinib is an investigational, once-daily pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated by Janssen Research and Development in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer and other solid tumours. FGFRs are a family of receptor tyrosine kinases which may be upregulated in various tumour cell types and may be

involved in tumour cell differentiation and proliferation, tumour angiogenesis, and tumour cell survival.[12] In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Therapeutics Ltd. to develop and commercialise erdafitinib.

About ibrutinib

Ibrutinib is a first-in-class Bruton's tyrosine kinase (BTK) inhibitor, which works by forming a strong covalent bond with BTK to block the transmission of cell survival signals within the malignant B-cells.[13] By blocking this BTK protein, ibrutinib helps kill and reduce the number of cancer cells, thereby delaying progression of the cancer.[14]

Ibrutinib is currently approved in Europe for the following uses:[15]

- Chronic lymphocytic leukaemia (CLL): As a single agent for the treatment of adult patients with previously untreated CLL, and as a single agent or in combination with bendamustine and rituximab (BR) for the treatment of adult patients with CLL who have received at least one prior therapy.
- Mantle cell lymphoma (MCL): Adult patients with relapsed or refractory mantle cell MCL.
- Waldenström's macroglobulinemia (WM): Adult patients who have received at least one prior therapy or in first-line treatment for patients unsuitable for chemo-immunotherapy.

The most common adverse reactions seen with ibrutinib include diarrhoea, neutropenia, haemorrhage (e.g., bruising), musculoskeletal pain, nausea, rash, and pyrexia.[15]

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using ibrutinib please refer to the Summary of Product Characteristics for further information.[15]

About daratumumab

Daratumumab is a first-in-class biologic targeting CD38, a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[16,17,18] Daratumumab is believed to induce tumour cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as well as through apoptosis, in which a series of molecular steps in a cell lead to its death.[19] A subset of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[19] Daratumumab is being evaluated in a comprehensive clinical development program across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[20,21,22,23,24,25,26,27,28] Additional studies are ongoing or planned to assess its potential for a solid tumour indication and in other malignant and pre-malignant

diseases in which CD38 is expressed, such as smouldering myeloma.[29,30,31,32] For more information, please see www.clinicaltrials.gov.

Daratumumab is currently approved in Europe for the following uses:[19]

- As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.
- In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

The most common adverse reactions seen with daratumumab include infusion reactions, fatigue, nausea, diarrhoea, muscle spasms, pyrexia, cough, dyspnoea, neutropenia, thrombocytopenia and upper respiratory tract infection. In addition, in combination with bortezomib, peripheral oedema and peripheral sensory neuropathy were frequently reported.[19]

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using daratumumab please refer to the Summary of Product Characteristics.[19]

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialise daratumumab.[33]

About apalutamide

Apalutamide is an investigational, next-generation oral androgen receptor (AR) inhibitor that blocks the androgen signalling pathway in prostate cancer cells.[34] Apalutamide inhibits the growth of cancer cells in three ways: by preventing the binding of androgen to the AR; by stopping the AR from entering the cancer cells; and by preventing the AR from binding to the DNA of the cancer cell.[34] Apalutamide received US FDA approval on February 14, 2018 for the treatment of non-metastatic CRPC.[35] On February 9, 2018 Janssen submitted a Marketing Authorisation Application to the European Medicines Agency (EMA).[36]

About abiraterone acetate

Abiraterone acetate plus prednisone / prednisolone is the only approved therapy in mCRPC that inhibits production of androgens (which fuel prostate cancer growth) at all three sources that are important in prostate cancer - the testes, adrenals and the tumour itself.[37,38]

Abiraterone acetate with prednisone / prednisolone is currently approved in Europe for the following uses:[37]

- 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 androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.
- The treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

The most common adverse reactions seen with abiraterone acetate plus prednisone / prednisolone include urinary tract infection, hypokalemia, hypertension, and peripheral oedema.[37]

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using abiraterone acetate plus prednisone / prednisolone please refer to the Summary of Product Characteristics.[37]

About the Janssen Pharmaceutical Companies

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/emea. Follow us at www.twitter.com/janssenEMEA for our latest news.

Cilag GmbH International; Janssen Biotech, Inc.; Janssen Oncology, Inc. and Janssen-Cilag International NV 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 erdafitinib, apalutamide, ibrutinib, daratumumab, and abiraterone acetate. 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-Cilag International NV, the Janssen Pharmaceutical Companies of Johnson & Johnson 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's subsequent Quarterly Reports on Form 10-Q and other 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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