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Treatment outcome data from *The Prostate Cancer Registry* presented for the first time at the 2016 European Society for Medical Oncology (ESMO) Congress

Copenhagen, Denmark, 10th October, 2016 – Janssen-Cilag International NV today presented the first reported primary treatment outcome data from *The Prostate Cancer Registry,* Europe's first and largest prospective study of men with metastatic castration-resistant prostate cancer (mCRPC), at the 2016 European Society for Medical Oncology (ESMO) Congress in Copenhagen, Denmark. The preliminary data suggest that chemotherapy-naïve patients benefit more from treatment than post-chemotherapy patients, and that after first line docetaxel treatment, patients have a higher prostate-specific antigen (PSA) response when treated with androgen receptor-targeted agents than with taxanes.[1]

"The Prostate Cancer Registry provides unique insights into the treatment of mCRPC patients from a large, real-world population. With enrolment now complete at over 3,000 patients across 16 countries, there is no other registry in advanced prostate cancer of this size that has produced such a large volume of data," said Dr Simon Chowdhury, Guy's Hospital, London. *"The Prostate Cancer Registry is helping us to address a critical gap in our understanding of the real-world management of patients with mCRPC. This involves studying patients who have high rates of comorbidities and use multiple medications, who are usually excluded from clinical trials. Every patient is different and it is extremely important for clinicians to be able to understand how men with mCRPC respond to medications to ensure that we chose the very best treatment for each individual. I look forward to seeing further data as the Registry continues."*

The preliminary data from *The Prostate Cancer Registry presented* at ESMO 2016 suggest that chemotherapy-naïve patients had a longer median time to next therapy (601 days for abiraterone acetate and 503 days for enzalutamide) than post-

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chemotherapy patients (428 days for abiraterone acetate and 366 days for enzalutamide) when treated with androgen receptor-targeted agents. Chemotherapy-naïve patients also had a higher PSA response than post-chemotherapy patients when treated with either androgen receptor-targeted agents or taxanes.

Data from the study also suggest that for patients who have had first line docetaxel treatment, PSA response at Month 3 was higher with androgen receptor-targeted agents (31% with abiraterone acetate and 39% with enzalutamide) than with taxanes (25% with docetaxel and 29% with cabazitaxel).

The Prostate Cancer Registry has enrolled over 3,000 mCRPC patients in 199 centres across 16 European countries. It aims to address the key medical and scientific questions concerning the optimal care of mCRPC patients in routine practice, by providing unique insights into how effective treatments are in a wider patient population, how their disease is managed and how patients live with the impact of their disease and treatment.

Jane Griffiths, Company Group Chairman, Janssen Europe, the Middle East and Africa (EMEA) said: "*Janssen is proud to support The Prostate Cancer Registry and be a part of this huge endeavour which has never been attempted before. Our aim is to help provide the very best treatments for patients and improve their outcomes. It is great to see preliminary data results of treatment outcomes in mCRPC being presented at ESMO 2016. This is just the beginning and we are excited to see even further data from the Registry emerging over the coming years.*"

Prostate cancer is the most commonly diagnosed cancer in men, with over 400,000 new cases diagnosed in Europe each year.[2] Latest prostate cancer figures show that there are currently three million men living with the disease in Europe.[3]

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NOTES TO EDITORS

About *The Prostate Cancer Registry*

The Prostate Cancer Registry was initiated in 2013 as a long-term commitment by Janssen to address optimal treatment of mCRPC in routine practice. The Registry was designed in consultation with specialists in mCRPC and examines patients being managed in a range of oncology and urology settings, with the aim of reflecting routine clinical practice.

Patients are enrolled upon initiating a mCRPC treatment or a period of surveillance, defined as not currently receiving an active treatment for castration resistance. The Registry is collecting data on a pan-European scale on patient demography and status, treatment sequencing and effectiveness, ongoing disease management, quality of life, medical resource utilisation and outcomes.

The first analysis was presented at the 2015 European Cancer Congress (ECC) in Vienna Austria and final analysis is planned for 2019.

The latest Prostate Cancer Registry animation can be viewed here.

About ZYTIGA (abiraterone acetate)

ZYTIGA is the only approved therapy that inhibits production of androgen, which fuels prostate cancer growth, via inhibiting the CYP17 enzyme complex present at three sources: the testes, adrenals and the tumour itself.

ZYTIGA has been approved in more than 90 countries and to date, has been prescribed to more than 269,500 men worldwide.

Indication[4]

In 2011, ZYTIGA in combination with prednisone/prednisolone was approved by the European Commission (EC) for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

In December 2012, the EC granted an extension of the indication for ZYTIGA permitting its use, in combination with prednisone or prednisolone, for the treatment of mCRPC, in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.[4]

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Further Information[4]

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using ZYTIGA, please refer to the summary of product characteristics, which is available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&mid=WC0b01ac058001d124

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.

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