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New data reveal that presence of metastases at initial prostate cancer diagnosis may have a critical impact on prognosis for metastatic castration-resistant patients

NOTE: this press release relates to ASCO 2016 Congress abstract #5024, poster board #281, presented 4 June 2016.¹

Beerse, Belgium, 4 June, 2016 – Janssen-Cilag International NV today announced that data from an interim analysis of *The Prostate Cancer Registry*, Europe's first and largest prospective study of men with metastatic castration-resistant prostate cancer (mCRPC), indicate that the presence of distant metastases (M1) at initial diagnosis may be a critical indicator of future treatment and prognosis for mCRPC patients.

The data, presented today at the American Society of Clinical Oncology (ASCO) 2016 Congress, Chicago, USA, described characteristics at study entry of men with mCRPC who had distant metastases at primary diagnosis (M1) as compared to those whose cancer had not metastasised at primary diagnosis (M0). The data demonstrated higher prostate-specific antigen (PSA) levels, increased incidence of bone lesions and slightly worse level of functioning, in terms of their ability to care for themselves, daily activity, and physical ability (measured by ECOG Scale of Performance Status) for patients with M1 at initial diagnosis compared to patients with no metastases (M0) at initial diagnosis.

- PSA levels were 34.4% higher (61.7 ng/mL vs 45.9 ng/mL) for M1 vs M0
- Incidence of bone lesions (>5) were 24% higher (51% vs 41%) for M1 vs M0
- ECOG Scale of Performance Status >2 were higher (17% vs 13%) for M1 vs M0

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"These data can help to better inform the way we treat mCRPC patients. It demonstrates that patients who present with metastases at diagnosis require particularly close attention from healthcare professionals to tackle the disease head on with prompt and effective treatment for the best possible outcome," said Dr Simon Chowdhury, Guy's Hospital, London. *"Real world data, such as these, provide us with valuable insight into the true patient journey. They include a wider population, such as men of a broader age range and with other existing health problems, than the more restricted and closely monitored populations seen in interventional clinical trials."*

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. The size of the database will enable analysis on sub-populations relevant to healthcare professionals. In this dataset, 1323 patients with mCRPC were analysed, including 549 who had M1 (41.5%) and 526 who had M0 (39.8%) disease at initial diagnosis, and 248 men for whom state of metastasis was not measurable (Mx, 18.7%) at initial diagnosis. Follow-up of these patients over time will clarify how these clinical differences and subsequent treatment may affect clinical outcome.

Jane Griffiths, Company Group Chairman, Janssen Europe, the Middle East and Africa (EMEA) said: *"Janssen is proud to be supporting The Prostate Cancer Registry, which is the largest of its kind in Europe. As there is currently limited data available on the everyday experience of mCRPC patients we hope that the insights from the trial will lead to an improvement in the quality of care and prognosis for men with mCRPC."*

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

-ENDS-

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.

About Janssen

Janssen-Cilag International NV is one of the Janssen Pharmaceutical Companies. Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, hepatitis C and tuberculosis) and cardiovascular and metabolic diseases (e.g. diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found on www.janssen-emea.com. Follow us on www.twitter.com/janssenEMEA for our latest news.

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include disease area strongholds that focus on haematologic malignancies and prostate cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may

help guide targeted, individualised use of our therapies; as well as safe and effective identification and treatment of early changes in the tumour microenvironment.

References:

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- ¹ Chowdhury S et al. The Prostate Cancer Registry: Do patients with metastatic castration-resistant prostate cancer (mCRPC) differ according to metastatic status at diagnosis? Poster presented at the American Society of Clinical Oncology (ASCO) 2016 Congress, 4 June, Chicago, USA. Poster Presentation. ASCO abstract #5024. Available at: http://abstract.asco.org/176/AbstView_176_161487.html. Last accessed May 2016.
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- ³ European Commission. CORDIS Express: Prevention, diagnosis and treatment of prostate cancer. Available at: http://cordis.europa.eu/news/rcn/122705_en.html. Last accessed September 2015.