

Media Enquiries:

Emily Bone
+44 (0)1494 658892
ebone1@its.jnj.com

Investor contacts:

Lesley Fishman
Phone: +1 (0)732 524 3922

First data from Europe's first and largest prospective observational study of metastatic castration-resistant prostate cancer (mCRPC) presented at the 2015 European Cancer Congress (ECC2015)

NOTE: this press release relates to ECC 2015 Congress abstract #2548 presented on Monday 28 September 2015 at 16:45 CET.¹

Vienna, Austria, 28 September, 2015 – Janssen-Cilag International NV today announced that data from the first analysis of the *The Prostate Cancer Registry* are being presented at the 2015 European Cancer Congress (ECC) in Vienna, Austria.¹ The Registry is the first and largest prospective study of patients with metastatic castration-resistant prostate cancer (mCRPC) in Europe. It aims to provide real world data to help improve the quality of care for men with mCRPC.

With the aim of enrolling a total of 3,000 patients, to date more than 2,500 mCRPC patients from 192 centres in 16 European countries have so far been enrolled. Patients in the study will be followed for up to three years. By collecting real world data from such a large patient population in both oncology and urology clinics, the Registry has the capacity to address the key medical and scientific questions concerning the optimal care of mCRPC patients in routine practice, such as treatment sequencing, treatment outcomes, impact on quality of life, medical resource utilisation and patient safety.

"Whilst the advent of new, effective treatments has benefitted many patients, for doctors, increased treatment options raise more questions about which are the right treatments to give individual patients and in what order," said Dr Simon Chowdhury, Guy's Hospital, London. *"The Registry follows patients we see in every day practice; patients with multiple co-morbidities such as heart*

disease and diabetes. The size and scope of the Registry will allow us to analyse large-scale datasets to better understand how we can best utilise the various therapeutic options and tailor treatment to our patients' individual needs. As the database matures, we can expect to keep building our knowledge on contemporary mCRPC management in daily practice."

The first analysis presented at ECC2015 indicates an enrolment of a broad range of patients with complex clinical presentations, reflecting the real-world nature of the population studied. Patients in the study have a mean age of 71.5 years and a high incidence of comorbidities (62.8%), the most common being cardiovascular disease (54.9%) and hypertension (44.6%). 79.2% of the patients enrolled were prescribed concomitant medications. 41.4 per cent of patients had previously received chemotherapy and 58.6 per cent were chemotherapy-naïve at enrolment.¹

Further analyses and data releases are being planned for early 2016.

Jane Griffiths, Company Group Chairman, Janssen Europe, the Middle East and Africa (EMEA) said: *"The Prostate Cancer Registry is a landmark observational study which Janssen is proud to be supporting. We expect The Registry to offer a fuller picture of the evolution of mCRPC management in routine practice. We anticipate the knowledge it provides will help to improve the care of patients with advanced prostate cancer."*

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 Europe³.

-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.

This first analysis reports on data of 505 patients enrolled between June 2013 and January 2014 and followed for up to 9 months.

About Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Metastatic castration-resistant prostate cancer occurs when cancer has metastasised (spread) beyond the prostate to other parts of the body and the disease progresses despite serum testosterone below castrate levels.⁴

The prostate is a gland in men that produces part of the seminal fluid and is located around the urethra (under the bladder). In some cases, cancer of the prostate can grow slowly. However, depending on factors including characteristics specific to the patient and the tumour, prostate cancer also can grow very quickly and spread widely.⁵

In 2012, an estimated 417,000 new cases of prostate cancer were diagnosed in Europe, and 92,200 men died from the disease.²

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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- 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.
- 4 Hotte SJ, SZytigad F. Current management of castrate-resistant prostate cancer. *Curr Oncol*. 2010 September; 17 (Supplement 2): S72–S79.
- 5 Mayo Clinic. Prostate Cancer. Available at: <http://www.mayoclinic.com/health/prostate-cancer/DS00043>. Last accessed September 2015.