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FOR IMMEDIATE RELEASE

**Janssen to present growing set of oncology data at the 2016 European Society
for Medical Oncology (ESMO) Congress**

NOTE: this press release relates to ESMO 2016 Congress abstracts #906O, #738P, #740P, #746P, #769TiP, #771TiP, #789p, #845TiP, #781PD and #1161P.

Beerse, Belgium, 28 September, 2016 – Janssen-Cilag International NV today announced data from ten company-sponsored abstracts will be presented at the 2016 ESMO Congress in Copenhagen, Denmark, on the 9th and 10th October 2016. The data feature four Janssen medicines spanning multiple disease areas including prostate, urothelial and blood cancer, and showcase Janssen’s broad portfolio in oncology and commitment to patients.

"The data to be presented at ESMO highlights the efficacy and safety profiles of Janssen treatments and also provides insights from a large, real-world prostate cancer patient population on how patients live with, and manage, their disease. Every patient with cancer will face his or her own unique journey and we are committed to helping redefine that journey. We hope that these findings will help us improve outcomes for cancer patients in the future," said Jane Griffiths, Company Group Chairman, Janssen European, Middle East and Africa (EMEA).

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Among the abstracts selected for presentation is data from the Prostate Cancer Registry, the first and largest prospective study of European patients with metastatic castration-resistant prostate cancer (mCRPC).

Also in prostate cancer, a follow-up analysis from the COU-AA-302 study, investigating long-term safety of ZYTIGA[®] (abiraterone acetate) for the treatment of mCRPC, will be presented. In addition, the design of the TITAN and ATLAS trials will be presented; the trials will study the efficacy and safety profiles of apalutamide, a new generation androgen receptor inhibitor, in patients with newly-diagnosed mCRPC.

In bladder cancer, Phase 1 data will be presented around urothelial carcinoma (UC) examining the safety, efficacy and tolerability in patients treated with the pan-fibroblast growth factor receptor (FGFR) inhibitor erdafitinib.

Haematological malignancy data to be featured includes results from the Phase 3 CASTOR study, evaluating DARZALEX[®] (daratumumab) in combination with bortezomib and dexamethasone, compared to bortezomib and dexamethasone alone in patients with multiple myeloma who received one or more prior lines of therapy. This study has been published in the [New England Journal of Medicine](#) and formed the basis for recent submissions to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), seeking to expand existing licenses for DARZALEX.¹

The following Janssen abstracts have been accepted for presentation at the 2016 ESMO congress:

- **Haematological Malignancies, Proffered Paper Session, 9th October, 11:00-12:00 CEST (Bern):**
 - 11:00-11:15: 906O - Phase 3 randomised study of daratumumab, bortezomib and dexamethasone (DVd) vs bortezomib and dexamethasone (Vd) in patients (pts) with relapsed or refractory multiple myeloma (RRMM): CASTOR²
- **Poster Display, 9th October, 13:00 – 14:00 CEST (Copenhagen, Hall E):**
 - 13:00-14:00: 738P - Meta-analysis of randomized clinical trials in metastatic castration resistant prostate cancer: Comparison of hypertension, neurological and psychiatric adverse events on enzalutamide and abiraterone acetate plus prednisone treatment³
 - 13:00-14:00: 740P - Safety of long-term (LT) treatment (tmt) of chemotherapy (chemo)-naïve metastatic castration-resistant prostate

cancer (mCRPC) patients (pts) with abiraterone acetate plus prednisone (AA+ P) for ≥ 4 years (yrs)⁴

- 13:00-14:00: 746P - The prostate cancer registry: Patient characteristics, treatments and preliminary outcomes from a large observational study of metastatic castration-resistant prostate cancer (mCRPC)⁵
- 13:00-14:00: 769 Trial in Progress (TiP) - ATLAS: A phase 3 trial evaluating the efficacy of apalutamide (ARN-509) in patients with high-risk localized or locally advanced prostate cancer receiving primary radiation therapy⁶
- 13:00-14:00: 771TiP - TITAN: A randomized, double-blind, placebo-controlled, phase 3 trial of apalutamide (ARN-509) plus androgen deprivation therapy (ADT) in metastatic hormone-sensitive prostate cancer (mHSPC)⁷
- 13:00-14:00: 789P - Pharmacokinetics (PK) of the pan-FGFR inhibitor erdafitinib in urothelial carcinoma⁸
- 13:00-14:00: 845TiP - Ongoing phase 2 study of erdafitinib (JNJ-42756493), a pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor, in patients (pts) with metastatic or unresectable urothelial carcinoma (M/UR UC) and FGFR gene alterations⁹
- **Genitourinary Tumours Non-Prostate, Poster Discussion Session, 9th October, 16:30-17:30 CEST (Athens):**
 - 17:10-17:30: 781PD - Safety and activity of the pan-fibroblast growth factor receptor (FGFR) inhibitor erdafitinib in phase 1 study patients with advanced urothelial carcinoma¹⁰
- **Poster Display, 10th October, 13:00 – 14:00 CEST (Copenhagen, Hall E):**
 - 13:00-14:00: 1161P - Utility of a targeted NGS oncology assay for circulating tumor DNA in a multi-histology clinical setting¹¹

Please note that all abstracts accepted for presentation at the ESMO congress are subject to the organisers' embargo policies.

-ENDS-

NOTES TO EDITORS

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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 - ³ Ruiz Gracia, P. Meta-analysis of randomized clinical trials in metastatic castration resistant prostate cancer: Comparison of hypertension, neurological and psychiatric adverse events on enzalutamide and abiraterone acetate plus prednisone treatment. Abstract #738P. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LXm#2z95v0T9>. Last accessed September 2016.
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 - ⁵ Chowdhury, S. The prostate cancer registry: Patient characteristics, treatments and preliminary outcomes from a large observational study of metastatic castration-resistant prostate cancer (mCRPC). Abstract #746P. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LWu#2z95v0qo>. Last accessed September 2016.
 - ⁶ Bossi, A. ATLAS: A phase 3 trial evaluating the efficacy of apalutamide (ARN-509) in patients with high-risk localized or locally advanced prostate cancer receiving primary radiation therapy. Abstract #769TiP. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LY6#2z95v0oF>. Last accessed September 2016.
 - ⁷ Chi, K. TITAN: A randomized, double-blind, placebo-controlled, phase 3 trial of apalutamide (ARN-509) plus androgen deprivation therapy (ADT) in metastatic hormone-sensitive prostate cancer (mHSPC). Abstract #771TiP. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LYf#2z95v0yr>. Last accessed September 2016.
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 - ⁹ Siefker-Radtke, A. Ongoing phase 2 study of erdafitinib (JNJ-42756493), a pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor, in patients (pts) with metastatic or unresectable urothelial carcinoma (M/UR UC) and FGFR gene alterations. Abstract #845TiP. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LYJ#2z95v0wX>. Last accessed September 2016.
 - ¹⁰ Soria, J.C. Safety and activity of the pan-fibroblast growth factor receptor (FGFR) inhibitor erdafitinib in phase 1 study patients with advanced urothelial carcinoma. Abstract #781PD. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LYX#2z94X0Jt>. Last accessed September 2016.
 - ¹¹ Eerkes, T. Utility of a targeted NGS oncology assay for circulating tumor DNA in a multi-histology clinical setting. Abstract #1161P. Available at: <https://cslide.ctimeetingtech.com/library/esmo/browse/search/LZj#2z95w0Yd>. Last accessed September 2016.