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NICE set to deny access to UK-discovered Zytiga® (abiraterone acetate) with androgen deprivation therapy (ADT) for men with aggressive, early prostate cancer

High Wycombe, 6 June 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today expressed disappointment at the National Institute for Health and Care Excellence (NICE) draft guidance not to recommend Zytiga (abiraterone acetate) plus androgen deprivation therapy (ADT) within its marketing authorisation, for men with untreated high-risk hormone-sensitive metastatic prostate cancer (mHSPC).[1]

Should the NICE Appraisal Consultation Document (ACD) become final, up to 4,400 men with this particularly aggressive form of prostate cancer[2] will be unable to access the treatment until their disease has progressed. Furthermore, around half of these patients[3] who are unable to tolerate conventional chemotherapy (docetaxel),[4] will be left with no life-prolonging treatment option at this early, but crucial stage in the treatment pathway. Abiraterone is the only licensed treatment for mHSPC that can delay chemotherapy and disease progression, prolong overall survival and maintain patients' quality of life.[5*]

Prostate cancer is the most common male cancer in the UK with around 47,700 new cases every year.[2] More men now die from prostate cancer than breast cancer in the UK[6] and life expectancy for those with mHSPC is approximately three years.[7]

Jennifer Lee, Director of Health Economics, Market Access and Reimbursement (HEMAR) and Advocacy at Janssen UK, said, "This is extremely disappointing news for men in the UK with mHSPC and their families. Many of these men are already living with the psychological burden of being diagnosed with an aggressive disease that has a poor prognosis and highly debilitating symptoms, which can greatly impact quality of life.[8] Such patients have the right to treatment choice, and the right to experience the life-extending benefits of a novel treatment, before their disease progresses."

She continued: "We firmly believe that the clinical effectiveness demonstrated in the multinational, Phase 3 LATITUDE study, means that abiraterone plus ADT should be made available routinely to NHS patients that need it, and we will continue to work closely with NICE to make this happen."

[*] The NICE ACD recommendation is not intended to affect treatment with abiraterone plus ADT that was started in the NHS before the guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

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Abiraterone is widely recognised as a success story for the UK life sciences industry, having been discovered at the Institute of Cancer Research and first trialled at The Royal Marsden Hospital. It is already recommended by NICE as clinically and cost effective later in the disease pathway as an option for treating metastatic castration-resistant prostate cancer before and after chemotherapy.[9,10]

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[11,12,13] ADT plus docetaxel has shown improved outcomes in mHSPC when compared to ADT alone, but many patients are not candidates for docetaxel and may benefit from alternative therapy.[14] Also, while the majority of patients initially start on ADT, it usually becomes less effective over time.[15,16,17] Clinical evidence suggests that abiraterone plus ADT could become the treatment of choice for men with mHSPC to maximise health outcomes and prolong quality of life.[18,19 ,20,21]

The closing date for comments on the NICE Appraisal Consultation Document on abiraterone is 27th June 2018.

-ENDS-

NOTES TO EDITORS

About the LATITUDE Trial[5]

The Phase 3, multinational, multicentre, randomised, double-blind, placebo-controlled LATITUDE study enrolled 1,199 newly diagnosed patients with metastatic prostate cancer that were naïve to conventional hormone treatments and was conducted at 235 sites in 34 countries in Europe, Asia-Pacific, Latin America, and Canada. Patients had to have at least two of the three following high-risk factors associated with poor prognosis:

- Gleason score ≥8
- ≥3 bone lesions
- presence of measurable visceral metastases

A total of 597 patients were randomised to receive ADT in combination with abiraterone acetate plus prednisone, while 602 patients were randomised to receive ADT and placebo.

- The median overall survival was significantly longer in the abiraterone group than in the placebo group (not reached vs. 34.7 months) (hazard ratio for death, 0.62; 95% confidence interval [CI], 0.51 to 0.76; P<0.001).
- The median radiographic progression-free survival (rPFS) was 33.0 months in the abiraterone group and 14.8 months in the placebo group (hazard ratio for disease progression or death, 0.47; 95% CI, 0.39 to 0.55; P<0.001).
- There was a 30% reduced risk of pain progression with abiraterone acetate versus placebo. The median time to pain progression was not reached in the abiraterone group and was 16.6 months in the placebo group (HR, 0.70; 95% CI, 0.58-0.83; P <.0001). Additionally, the risk of developing a skeletal-related event was 30% lower with abiraterone acetate versus ADT (HR, 0.7; 95% CI, 0.54-0.92; P = .0086). The risk of starting chemotherapy was reduced by 56% with abiraterone acetate versus ADT alone (HR, 0.44; 95% CI, 0.35-0.56; P<.0001).

The safety profile of ADT in combination with abiraterone acetate plus prednisone was consistent with prior studies in patients with mCRPC. The most common adverse events were elevated incidences of mineralocorticoid-related hypertension and hypokalaemia in the ADT in combination with abiraterone acetate plus prednisone arm compared with ADT and placebos.[5] The observed degrees of hypertension and hypokalaemia were both medically manageable. They only rarely required treatment discontinuation and seldom led to serious adverse events.[5]

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About abiraterone acetate

Indications[22]

Abiraterone acetate is indicated with prednisone or prednisolone for:

- 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.

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using abiraterone acetate, please refer to the summary of product characteristics, available at: https://www.medicines.org.uk/emc/product/2381/smpc.

About Janssen

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.co.uk. Follow us at www.twitter.com/JanssenUK.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development including a potential new indication. 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 materialise, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties and delays; changes in behaviour and spending patterns or financial distress 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 description 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 January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent 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 or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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