FOR UK CONSUMER HEALTH, UK TRADE AND UK MEDICAL MEDIA ONLY
Under embargo until SMC publishes decision on 13th January 2020, after 14:00 GMT*

Media Enquiries:
Flavia Suleyman
FSuleyma@ITS.JNJ.com
Phone: 07769 949 797

Rita Martins
Phone: 0207 492 1788

Investor Relations:
Christopher De lOrefice
Phone: +1 732 524 2955

Scottish Medicines Consortium recommends Zytiga® (abiraterone acetate) in combination with prednisone and androgen deprivation therapy (ADT) for men with aggressive, early prostate cancer for use in NHS Scotland

High Wycombe, 13 January 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today welcomed the Scottish Medicines Consortium (SMC) decision to recommend Zytiga (abiraterone acetate) with prednisone or prednisolone plus androgen deprivation therapy (ADT) for use in NHS Scotland for the treatment of adult men with newly diagnosed high-risk, metastatic hormone-sensitive prostate cancer (mHSPC).[1]

The SMC made its recommendation after considering evidence from the multinational, Phase 3 LATITUDE study[2] (comparing abiraterone and ADT with ADT alone) alongside data from the ongoing STAMPEDE study[3] where necessary (comparing abiraterone plus ADT with ADT alone, and with docetaxel plus ADT). Combining abiraterone with ADT consistently demonstrated superiority over ADT alone in terms of delaying disease progression, improving quality of life and extending overall survival.[2,3]

Prostate cancer is the most common male cancer in the UK with around 47,700 new cases every year.[4] More men now die from prostate cancer than women from breast cancer in the UK.[5] Annually, there are 3,518 new cases of prostate cancer in Scotland,[6] with an estimated population of 460 who could be eligible for abiraterone acetate in combination with prednisone or prednisolone and ADT.[1] Life expectancy for those with newly diagnosed high-risk mHSPC is typically three years on conventional hormone therapy.[7]

“This is a landmark decision which has the potential for positively changing the lives of men in Scotland who have advanced prostate cancer when first diagnosed,” said Steve Allen, Patient Representative, Tackle Prostate Cancer. “They now have a choice of therapy

*Embargo lifts when the SMC document (see reference 1) appears on the SMC website, currently scheduled for the date and time specified at the top of the release

Date of preparation: January 2020
Job number: CP-133077

that can be used in addition to standard hormone therapy. The SMC are to be applauded for this decision which will allow these patients to have an improved quality of life."

The guidance was issued following a pragmatic review of the evidence within a six-month period. Following a full submission by Janssen in June 2019, the SMC assessed abiraterone through the Patient and Clinician Engagement (PACE) process due to the orphan-sized patient population.[1] The PACE committee recognised the severity of the condition, the need for alternative treatment options in this setting, and the particular value abiraterone offers to patients who are unsuitable for chemotherapy (docetaxel) at diagnosis.[1] It also highlighted the positive impact abiraterone has on patients' quality of life and independence, as well as the considerable benefit to families and carers.[1]

Abiraterone is the only licensed treatment for newly diagnosed mHSPC which can delay chemotherapy and disease progression, prolong survival and maintain patients' quality of life.[2] Conventional chemotherapy (docetaxel) has been shown to provide significant benefit on overall survival, however it is associated with clinically significant toxicities[8] and, until the recommendation of abiraterone, patients had no other life-extending treatment option at this early stage in their treatment pathway. Abiraterone now fulfils this considerable unmet need in Scotland for patients unsuitable for treatment with docetaxel.[1]

"Janssen is pleased that the SMC has accepted abiraterone for use within NHS Scotland for eligible patients and applauds the SMC's pragmatic approach and flexibility in reaching this positive recommendation so quickly," said Jennifer Lee, Director of Health Economics, Market Access and Reimbursement (HEMAR) and Advocacy at Janssen UK. "We recognise this outcome results in a discrepancy in access between patients in Scotland and those in the rest of the UK and are currently working closely with NICE to ensure that men who need it will also be able to access abiraterone routinely within the NHS before their disease progresses."

Abiraterone was submitted to the National Institute for Health and Care Excellence (NICE) in February 2018, but an outcome has yet to be reached. Janssen continues to work with NICE and NHS England to find a solution for patients across the UK. Abiraterone 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]

Discovered at the Institute of Cancer Research and first trialled at The Royal Marsden Hospital, abiraterone is widely recognised as a success story for the UK life sciences industry.

-ENDS-

About abiraterone acetate

Indications[11]

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 the LATITUDE Trial[2]

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 LATITUDE study reached final analysis after a median follow-up of 51.8 months.

- The median overall survival was significantly longer in the abiraterone group than in the placebo group (53.3 months vs 36.5 months) (hazard ratio [HR]for death, 0.66; 95% confidence interval [CI], 0.56 to 0.78; P<0.0001).
- The median radiographic progression-free survival (rPFS) was 33.0 months in the abiraterone group and 14.8 months in the placebo group (HR for disease progression or death, 0.47; 95% CI, 0.39 to 0.55; P<0.001).

- There was a 28% reduced risk of pain progression with abiraterone versus placebo. The median time to pain progression was 47.4 months in the abiraterone group and was 16.6 months in the placebo group (HR, 0.72; 95% CI, 0.61 to 0.86; P<0.0001). Additionally, the risk of developing a skeletal-related event was 25% lower in the abiraterone group than in the placebo group (HR, 0.75; 95% CI, 0.60 to 0.95; P=0.0086). The risk of starting chemotherapy was reduced by 49% with abiraterone compared with placebo (HR, 0.51; 95% CI, 0.41 to 0.63; 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. The observed degrees of hypertension and hypokalaemia were both medically manageable. They only rarely required treatment discontinuation and seldom led to serious adverse events.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/uk. Follow us at www.twitter.com/JanssenUK. Janssen-Cilag Limited is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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