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First-in-class treatment Imbruvica®▼ (ibrutinib) approved by the National Institute for Health and Care Excellence (NICE) for patients with Chronic Lymphocytic Leukaemia (CLL)

High Wycombe, 25th November 2016 – Janssen today announced that the National Institute for Health and Care Excellence (NICE) has published its Final Appraisal Determination (FAD) recommending Imbruvica®(ibrutinib), as a treatment option for adults with chronic lymphocytic leukaemia (CLL), who have had at least one prior therapy or who have a 17p deletion or TP53 mutation, and in whom chemo-immunotherapy is unsuitable.[1] Around 3,400 people each year are diagnosed with CLL in the UK, with the majority of those affected being over the age of 70 years old.[2]

Ibrutinib is the first in a new class of medicines known as Bruton's tyrosine kinase (BTK) inhibitors, with a unique and targeted mode of action. It has been designed to specifically block the BTK protein from causing malignant B cells to multiply and spread.[3] The FAD recommendation was based on the results of multiple trials, including RESONATE (PCYC-1112)[4] and PCYC-1102/3.[5]

NICE concluded that ibrutinib represents a clinically and cost effective treatment for patients with CLL. The UK now joins 39 countries in making ibrutinib routinely available to patients with this form of cancer.

Jennifer Lee, Director of Health Economics, Market Access & Reimbursement at Janssen UK, said, "This is very welcome news for patients with CLL, who will now be entitled to access ibrutinib via routine commissioning, and will in turn, free up much needed resources in the Cancer Drugs Fund. Janssen is dedicated to ensuring that patients with blood cancer have access to the most effective therapies, and we keenly await a similar positive decision by NICE for patients with mantle cell lymphoma and Waldenström macroglobulinemia, who currently have limited treatment options available to them. It is therefore our priority to

continue to work with NICE and NHS England to ensure that all patients who need ibrutinib will have access to it in the future."

#ENDS#

About ibrutinib
Ibrutinib is a BTK inhibitor, which works by forming a covalent bond with the BTK protein to block the transmission of cell survival signals within the malignant B cells. It has demonstrated rapid absorption and an ability to eliminate cancer cells.[6]

Imbruvica is indicated as follows:[7]

- as a single agent for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).
- as a single agent for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) (see section 5.1).
- as a single agent or in combination with bendamustine and rituximab (BR) for the treatment of adult patients with CLL who have received at least one prior therapy.
- as a single agent for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.

Adverse events should be reported ▼. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Janssen-Cilag Ltd on 01494 567447.

About Chronic Lymphocytic Leukaemia (CLL)
CLL is the most common type of leukaemia, accounting for 37% of all leukaemia cases, with the majority of new diagnoses occurring in people over 60.[8] In this age group, CLL patients have approximately a 70% chance of surviving 5 years after diagnosis.[9]

About Mantle Cell Lymphoma (MCL)
MCL is a rare type of B-cell lymphoma with approximately 500 people diagnosed each year in the UK[10] MCL is an aggressive, chronic and incurable disease. MCL patients have approximately 27% chance of surviving 5 years after diagnosis.[11]

About Waldenström macroglobulinemia (WM)
Waldenström macroglobulinemia is a rare type of slow growing non-Hodgkin lymphoma usually affecting people over the age of 65. Around 400 patients are diagnosed with WM each year in the UK.[12]

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About RESONATE

RESONATE™ (PCYC-1112) is a multi-centre, international, open-label, randomised study that investigated ibrutinib monotherapy versus ofatumumab monotherapy in relapsed or refractory patients with CLL (n=391) who were ineligible for purine analogue treatment.[4]

The results from the study showed single agent ibrutinib significantly improved progression-free survival (PFS), overall survival (OS) and overall response rate (ORR) in this difficult-to-treat patient population, regardless of baseline characteristics.[4]

The median PFS in the ofatumumab arm was 8.1 months and was not reached in the ibrutinib arm because progression events occurred more slowly. The hazard ratio for progression or death in the ibrutinib group was 0.22 (95% confidence interval [CI], 0.15 to 0.32; P<0.001).[4] The OS median was not reached in either arm, but ibrutinib, as compared with ofatumumab, significantly prolonged the rate of overall survival (hazard ratio for death in the ibrutinib group, 0.43; 95% CI, 0.24 to 0.79; P = 0.005).[4] Results were consistent across all baseline sub-groups, including those with 17p deletion.[4]

Safety profile of ibrutinib

The most commonly occurring adverse reactions (≥ 20%) were diarrhoea, neutropenia, haemorrhage (e.g., bruising), musculoskeletal pain, nausea, rash, and pyrexia. The most common grade 3/4 adverse reactions (≥ 5%) were neutropenia, pneumonia, thrombocytopenia, and febrile neutropenia.[7]

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.

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

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