Scottish ‘yes’ for breakthrough lung cancer treatment
triggers UK survival lottery

(Uxbridge, Middlesex, 12 July 2016) – Bristol-Myers Squibb today announced that the Scottish Medicines Consortium (SMC), the equivalent of the National Institute for Health and Care Excellence (NICE) in Scotland, has recommended the breakthrough cancer immunotherapy Opdivo® (nivolumab) to treat NHS patients with locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) whose disease has progressed after prior chemotherapy. While the news is positive for Scottish patients, the decision could trigger a UK survival lottery. The assessment of nivolumab by NICE is currently ongoing, meaning that the treatment remains unavailable for NHS patients living in England; it also remains unavailable in Wales and Northern Ireland. If NICE upholds its draft guidance not to recommend the use of nivolumab, treatment options for patients outside of Scotland will continue to be limited to a chemotherapy first approved nearly 20 years ago.

Nivolumab is the first in a class of medicines (PD-1 immune checkpoint inhibitors) for the treatment of lung cancer patients. It has an innovative mode of action that works by harnessing the ability of the immune system to fight this type of advanced lung cancer as well as advanced forms of skin and kidney cancer.

“Today’s decision gives Scottish NHS patients the chance to benefit from one of the biggest treatment advances in this type of lung cancer for decades and one that has the potential to change future survival expectations.” said Johanna Mercier, General Manager of Bristol-Myers Squibb UK & Ireland. “While this decision is positive news for lung cancer patients in Scotland, it will further compound the disappointment of patients in the rest of the UK, who are still waiting for access to this medicine. This demonstrates how antiquated the current UK system for reviewing new cancer medicines is and the disparity that it creates for patients and their families. We call on the UK Government to bring an end to the outdated processes that, in 2016, still mean that a person’s ability to access a cancer medicine on the NHS is determined not by their needs, but by where they live.”
In a pivotal Phase III study of 272 patients, treatment in the nivolumab arm (n=135) was shown to achieve significantly superior survival rates with 42% of patients still alive at one-year compared to 24% of those treated with docetaxel (n=137). Severe treatment-related adverse events occurred less frequently with nivolumab (out of 131 patients treated with nivolumab, 7% had grade 3-4 adverse events compared to 55% of 129 patients treated with docetaxel).

The disparity in access to nivolumab focuses on patients with a form of advanced lung cancer, which continues to be a growing health burden in the UK today. In 2012, over 44,500 people in the UK were diagnosed with all types of lung cancer. In the same year, over 35,000 deaths were attributable to the disease - more than breast and bowel cancer deaths combined. UK survival rates continue to lag almost a decade behind some other comparable European countries with around 80% of those diagnosed with advanced disease dying within one year.

# ENDS #
NOTES TO EDITORS

Data supporting the use of nivolumab

The data supporting the use of nivolumab in squamous NSCLC is based on a Phase III study comparing nivolumab to docetaxel, published in The New England Journal of Medicine in May 2015.

This study assessed the efficacy and safety of nivolumab in adult patients with advanced squamous cell NSCLC whose disease had progressed during or after one prior platinum containing chemotherapy regimen. Treatment with nivolumab (n=135) was shown to achieve significantly superior survival rates, with 42% (n=135, 95% confidence interval [CI] = 34-50) of patients still alive at one year compared with 24% (n=137, 95% CI = 17-31) of those treated with docetaxel.

Severe treatment-related adverse events occurred less frequently with nivolumab (out of the 131 patients treated with nivolumab, 7% had grade 3-4 adverse events compared to 55% of 129 patients treated with docetaxel). The majority of adverse reactions for nivolumab were mild to moderate (grade 1 or 2). Due to nivolumab’s mechanism of action, it causes immune-related adverse reactions, most of these, including severe reactions, are resolved following initiation of appropriate medical therapy or withdrawal of nivolumab.

About nivolumab

In Europe, nivolumab is licensed as monotherapy under the brand name Opdivo® for the treatment of adult patients with:

- Advanced (unresectable or metastatic) melanoma
- Locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy
- Advanced renal cell carcinoma after prior therapy

In addition, nivolumab is licensed in combination with ipilimumab for the treatment of adult patients with advanced (unresectable or metastatic) melanoma.

Bristol-Myers Squibb has a broad, global development programme to study nivolumab in multiple tumour types consisting of more than 50 trials – as monotherapy or in combination with other therapies – in which more than 8,000 patients have been enrolled worldwide.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com
Bristol-Myers Squibb & Immuno-Oncology: Advancing Oncology Research

At Bristol-Myers Squibb, we have a vision for the future of cancer care that is focused on Immuno-Oncology, now considered a major treatment choice alongside surgery, radiation, chemotherapy and targeted therapies for certain types of cancer.

We have a comprehensive clinical portfolio of investigational and approved Immuno-Oncology agents, many of which were discovered and developed by our scientists. Our ongoing Immuno-Oncology clinical programme is looking at broad patient populations across multiple solid tumours and haematological malignancies, with the intent of powering our trials for overall survival and other important measures like durability of response.

We pioneered the research leading to the first regulatory approval for the combination of two Immuno-Oncology agents, and continue to study the role of combinations in cancer.

We are also investigating other immune system pathways in the treatment of cancer including CTLA-4, CD-137, KIR, SLAMF7, PD-1, GITR, CSF1R, IDO, and LAG-3. These pathways may lead to potential new treatment options – in combination or monotherapy – to help patients fight different types of cancers.

Our collaboration with academia, as well as small and large biotech companies is responsible for researching the potential Immuno-Oncology and non-Immuno-Oncology combinations, with the goal of providing new treatment options in clinical practice. At Bristol-Myers Squibb, we are committed to changing survival expectations in hard-to-treat cancers and the way patients live with cancer.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.b-ms.co.uk.

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References


