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ASIA EDITION

China approves country's first immunotherapy drug for cancer

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BMS's Opidivo is the first and only PD-1 inhibitor approved in China opens a new era of Immuno-Oncology treatment for a type of lung cancer

Bristol Myers Squibb recently announced that the China National Drug Administration (CNDA) has approved Opdivo (nivolumab injection) for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior platinum-based chemotherapy in adult patients without EGFR or ALK genomic tumor aberrations.

This is China's first and only PD-1 inhibitor and is the only Immuno-Oncology (I-O) agent to demonstrate a survival benefit compared with chemotherapy, based on data from the pivotal Phase 3 CheckMate -078 trial, in which 90% of the patients enrolled were Chinese.

"Lung cancer is a major public health issue in China, representing the highest incidence and mortality among all cancers in the country," said Professor Yi-Long Wu, a tenured director of Guangdong General Hospital and the chair of the Chinese Thoracic Oncology Group. "With most lung cancer patients already at an advanced stage when diagnosed, prolonging survival is an important goal. The approval of *Opdivo* as the first I-O agent in China is a significant therapeutic advance and is great news for patients and clinicians alike, offering for the first time an I-O treatment option that is proven to extend survival in predominantly Chinese patients with previously treated NSCLC."

The approval is based on results from the Phase 3 CheckMate -078 trial of Opdivo versus chemotherapy among patients with previously treated NSCLC, findings from which were presented at the American Association for Cancer Research Annual Meeting in April 2018. In November 2017, the trial was stopped early because the independent Data Monitoring Committee concluded that *Opdivo* demonstrated superior overall survival compared with chemotherapy. The application later received priority review by the Center for Drug Evaluation in China.

Mr Murdo Gordan executive vice president and chief commercial officer, Bristol-Myers Squibb, commented, "With approvals in more than 60 countries, *Opdivo* is a global standard of care for previously treated NSCLC, and we are proud to bring this foundational I-O treatment option to patients and physicians in China."

"We are thrilled to be able to bring this proven treatment, Opdivo, which has demonstrated superior overall survival versus

chemotherapy in previously treated NSCLC patients in China, and are committed to working with stakeholders to ensure patients can quickly access *Opdivo*," said Fouad Namouni, M.D., head of development, Oncology, Bristol-Myers Squibb. "With more than 7,500 cancer deaths per day estimated in China, we will continue to work with urgency to integrate the unmet treatment needs of Chinese patients in our ongoing I-O global development program, with the goal of bringing them innovative therapies as quickly as possible."