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**ONO submits additional indication application for OPDIVO® (generic name: Nivolumab) for the treatment of patients with unresectable, advanced or recurrent non-small cell lung cancer**

ONO PHARMACEUTICAL CO.,LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") announced today that it has submitted an additional indication application for the human anti-human programmed cell death-1 (PD-1) monoclonal antibody "OPDIVO® 20mg, 100mg Inj." (OPDIVO) for the "treatment of patients with unresectable, advanced or recurrent non-small cell lung cancer (NSCLC)", including the data from clinical trial that evaluated patients with advanced non-squamous NSCLC. In addition, it submitted an additional indication application for the "treatment of patients with unresectable, advanced or recurrent NSCLC (except non-squamous cell carcinoma)" in Japan in April 2015.

Lung cancer is a form of malignant tumor that arises from cells in the trachea, bronchi, and alveoli. It is one of the leading causes of cancer-related death, responsible for approximately 1.6 million deaths worldwide each year. In Japan, NSCLC is the most common type of lung cancer, accounting for about 85% of lung cancer cases. Of patients with NSCLC, about 80% have non-squamous NSCLC, and about 20% squamous NSCLC, so there is an unmet need for new treatments for patients with NSCLC that cannot be removed by surgery and has become resistant to existing treatments, as they have an extremely poor prognosis, and currently available therapeutic options do not produce a significant improvement.

OPDIVO is the world's first immune checkpoint inhibitor blocking the PD-1/PD-1 ligand pathway proven to extend overall survival in patients with advanced non-squamous NSCLC previously treated with chemotherapy. The interim analysis of a phase III clinical trial (CheckMate-057) ,

open-label randomized clinical trial, conducted outside Japan showed that OPDIVO improved overall survival (OS), with a 27% reduction in the risk of death or disease progression, compared with standard of care(docetaxel). The median OS was 12.2 months (95% CI: 9.7, 15.0) in the OPDIVO group versus 9.4 months (95% CI: 8.0, 10.7) in the docetaxel group.

OPDIVO, the world's first human anti-human PD-1 monoclonal antibody, was approved for the "treatment of patients with unresectable melanoma" in Japan in July 2014. Outside Japan, OPDIVO was approved under accelerated approval in the USA in December 2014 for the "treatment of patients with unresectable or metastatic melanoma and disease progression following Yervoy® (generic name: ipilimumab) and, if BRAF V600 mutation positive, a BRAF inhibitor". In March 2015, it was also additionally approved in the USA for the "treatment of patients with advanced squamous NSCLC with progression or recurrence on or after platinum-based chemotherapy". In addition, EU approved OPDIVO for the "treatment of advanced (unresectable or metastatic) melanoma in adults".

"OPDIVO is a therapeutic antibody that acts by a novel mechanism and has the potential to provide benefits in multiple cancer types such as melanoma, NSCLC, and renal cell carcinoma. We hope to receive the approval early and offer the new treatment option for the treatment of patients with NSCLC," said Gyo Sagara, the President, Representative Director and CEO of ONO.

**About the ONO PHARMACEUTICAL and Bristol-Myers Squibb Collaboration**

In 2011, through a collaboration agreement with ONO PHARMACEUTICAL, Bristol-Myers Squibb expanded its territorial rights to develop and commercialize OPDIVO globally except in Japan, South Korea and Taiwan, where ONO had retained all rights to the compound at the time. In July 2014, ONO and Bristol-Myers Squibb further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.