December 11, 2015

ONO submits manufacturing and marketing approval partial amendment application for OPDIVO® (generic name: nivolumab) for treatment of patients with unresectable or metastatic renal cell carcinoma in Japan

ONO PHARMACEUTICAL CO.,LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") announced today that it has submitted a manufacturing and marketing approval partial amendment application for the human anti-human PD-1 (programmed cell death-1) monoclonal antibody "OPDIVO® 20mg, 100mg Inj." (OPDIVO) for the treatment of patients with unresectable or metastaic renal cell carcinoma in Japan.

Renal cell carcinoma (RCC) occurs in adult renal parenchyma and is the most common type of kidney cancer, accounting for more than 110,000 deaths worldwide each year. At present, there is no drug which demonstrates the extension of overall survival (OS) in patients with unresectable or metastatic RCC, so the development of new treatment is expected.

OPDIVO is the immune checkpoint inhibitor which blocks the interaction of the PD-1 receptor with its ligands and first demonstrated OS benefit in patients with unresectable by surgical operation or metastatic RCC who have received prior anti-angiogenic therapy in the world. In the interim analysis of CheckMate -025 trial, open-label and randomized Phase 3 study which was conducted including Japan, OPDIVO demonstrated a median OS of 25 months (95% CI: 21.7-NE) versus 19.6 months (95% CI: 17.6-23.1) for everolimus, offering a significant OS extension. Clinical results from CheckMate -025 trial were recently presented at the 2015 European Cancer Congress with simultaneous publication in The New England Journal of Medicine.

In Japan, OPDIVO is the first human anti-human PD-1 monoclonal antibody to receive regulatory approval for the treatment of patients with unresectable melanoma anywhere in the world in July 2014.
Also, outside of Japan, Bristol Myers Squibb, with whom we collaborate in Japan, Korea and Taiwan, currently has regulatory approval for OPDIVO in more than 40 countries globally. In the USA, OPDIVO is approved for treatment of metastatic squamous and non-squamous non-small

cell lung cancer (NSCLC) after progression on or after platinum-based chemotherapy OPDIVO or other first line therapy, respectively. Also, in the USA OPDIVO is approved for the treatment of unresectable or metastatic melanoma as a single agent and as a single agent following disease progression following Yervoy® (generic name: ipilimumab) and, if BRAF V600 mutation positive, a BRAF inhibitor. OPDIVO is also approved in combination with Yervoy for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma, the first combination of a PD-1 immune checkpoint inhibitor with a CTLA4 immune checkpoint inhibitor. Furthermore, OPDIVO was approved for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy,

In the EU, OPDIVO was approved for the treatment of advanced (unresectable or metastatic) melanoma in adults regardless of BRAF status and for the treatment of locally advanced or metastatic squamous NSCLC after prior chemotherapy.

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.

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