

April 11, 2016

ONO Announces Sales Results of OPDIVO[®] (Nivolumab), Antineoplastic Agent for Fiscal Year 2015 and its Sales Forecasts for Fiscal Year 2016

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; “ONO”) announced today the sales results of OPDIVO[®] (Nivolumab) intravenous infusion 20mg, 100mg (“OPDIVO”), a human anti-human PD-1 (programmed cell death-1) monoclonal antibody, for the fiscal year 2015 ended March (April 1, 2015 – March 31, 2016) and sales forecasts for the fiscal year 2016 ending March (April 1, 2016 – March 31, 2017).

OPDIVO is a first human anti-human PD-1 monoclonal antibody to receive the manufacturing and marketing approval for the indication of unresectable malignant melanoma in July 4, 2014 in Japan or anywhere in the world. OPDIVO was also granted for additional indication of unresectable, advanced or recurrent non-small cell lung cancer (NSCLC) in December 17, 2015.

The sales of OPDIVO for the fiscal year 2015 ending March was expected to be ¥3.5 billion at the beginning of the period when the indication was only limited to malignant melanoma. The full-year sales forecast was revised to be ¥5.5 billion in the summary of financial statements of the 2nd quarter of the fiscal year 2015 ending March (disclosed on November 4, 2015). In addition, taking into consideration additional approval for the indication of OPDIVO for unresectable, advanced or recurrent NSCLC, the sales forecast was increased by ¥12 billion to ¥17.5 billion from the previous forecast. The revised sales forecast was disclosed in the summary of financial statements of the 3rd quarter of the fiscal year 2015 ending March (February 2, 2016). However, the sales for the fiscal year 2015 ended March ultimately resulted in exceeding further from the previous sales forecasts.

Taking the above sales trend of OPDIVO into account, ONO will announce the sales forecasts of OPDIVO for the fiscal year 2016, prior to the announcement of the consolidated financial results for the fiscal year 2015.

ONO will disclose the consolidated financial results for the fiscal year 2015 and the financial forecasts for the fiscal year 2016, in the summary of financial statements (IFRS) of the fiscal year 2015 (scheduled for May 11, 2016).

Sales of OPDIVO

Sales results of fiscal year 2015 (April 1, 2015 – March 31, 2016) and sales forecast of fiscal year 2016 (April 1, 2016 – March 31, 2017)

(Millions of yen)

	Sales*
Revised sales forecasts for FY 2015 (Feb. 2, 2015)	17,500
Sales results for FY 2015	21,200
Sales forecasts for FY 2016	126,000

* Sales: based on wholesale price

(Reference 1) Changes in the estimated number (cumulative) of patients treated with OPDIVO for the treatment of malignant melanoma and NSCLC in Japan

	Number of treated patients
Up to December 2015	1,357
January 2016	2,063
February 2016	3,483
March 2016	4,888

Note: Calculated based on the scheduled treatment at the time of entry in the post-marketing use-result survey (all case survey)

(Reference 2) Estimated number of patients newly treated with OPDIVO in the fiscal year 2016

	Melanoma (pats)	NSCLC (pats)
Estimated number of patients newly treated with OPDIVO (Apr 2016 – Mar 2017)	450	15,000

The above sales forecasts are made based on information available as of the date of the announcement and actual results may differ from the forecasted figures according to future various factors.

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