July 27, 2016

ONO Submits Supplemental Application of OPDIVO® (Nivolumab) for Recurrent or Metastatic Head and Neck Cancer for a Partial Change in Approved Items of Manufacturing and Marketing Approval in Japan

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") and Bristol-Myers Squibb Company (NYSE: BMY) announced today that ONO submitted a supplemental application for OPDIVO® Intravenous Infusion 20 mg and 100 mg ("OPDIVO"), the human anti-human PD-1 (programmed cell death-1) monoclonal antibody, for the treatment of recurrent or metastatic head and neck cancer for a partial change to the approved items of the manufacturing and marketing approval in Japan.

This regulatory application is based on the results of a pivotal Phase III open-label, randomized clinical trial, CheckMate-141. Based on a planned interim analysis, this trial was stopped early in January 2016 because an assessment conducted by the independent Data Monitoring Committee concluded the study met its primary endpoint of overall survival in patients with recurrent or metastatic squamous cell carcinoma of the head and neck receiving OPDIVO after platinum therapy compared to investigator's choice of therapy.

Head and neck cancer (HNC) is a general term describing malignant tumors occurring in the head and neck regions, such as the lip, oral cavity, nasal cavity, paranasal sinuses, epipharynx, oropharynx, hypopharynx, larynx, large salivary gland, thyroid gland or mucosal melanoma. It is estimated that there are about 24,000 affected patients with HNC except thyroid gland cancer annually in Japan*. Platinum-based chemotherapy has been recommended in patients with recurrent or metastatic HNC. To date, no available therapy has demonstrated an extension of overall survival in those patients who recurrently progress early after chemotherapy and are not applicable to the local treatment. Therefore, new treatment options are needed in this patient population.

OPDIVO is the first human anti-human PD-1 monoclonal antibody to receive manufacturing and marketing approval for treatment of unresectable melanoma in July 2014 in Japan or anywhere in the world. OPDIVO also received approval for the indication of unresectable, advanced or recurrent non-small cell lung cancer in December 2015. Supplemental applications have been submitted for the indications of renal cell cancer and Hodgkin lymphoma. Outside of Japan, OPDIVO has regulatory approval in 54 countries as part of the ONO - Bristol-Myers Squibb (BMS) collaboration.

In Japan, ONO and BMS (and BMS Japan subsidiary, BMSKK) have formed a strategic partnership that includes co-development, co-commercialization, and co-promotion of multiple immunotherapies for patients with cancer in Japan, South Korea and Taiwan.

About CheckMate-141

CheckMate-141 is a Phase 3 open-label, randomized trial, evaluating OPDIVO in patients with recurrent or metastatic squamous cell carcinoma of the head and neck after platinum therapy compared to investigator's choice of therapy (methotrexate, docetaxel, or cetuximab). In the trial, which evaluated overall survival (OS) as the primary endpoint, patients treated with OPDIVO experienced a 30% reduction in the risk of death, with a median OS of 7.5 months (95% CI: 5.5-9.1) compared to 5.1 months (95% CI: 4.0-6.0) for investigator's choice (HR=0.70 [97.73% CI: 0.51-0.96] p=0.0101). The one-year survival rate for OPDIVO was 36% compared to 16.6% for investigator's choice. The safety profile of OPDIVO in CheckMate-141 was consistent with prior studies, with no new safety signals identified.

About ONO PHARMACEUTICAL CO., LTD.

ONO PHARMACEUTICAL CO., LTD, headquartered in Osaka, Japan, is an R&D-oriented pharmaceutical company committed to creating and developing innovative medicines in specific areas. It focuses especially on the oncology and diabetes areas. For more information, please visit at www.ono.co.jp.

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 at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

About the ONO and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement with Bristol-Myers Squibb, ONO granted BMS 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.

*: Monitoring of Cancer Incidence in Japan (MCIJ 2012), National Cancer Center, Center for Cancer Control and Information Services

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