ONO PHARMACEUTICAL CO.,LTD.

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Ono Enters into Collaboration Agreement on Combination Therapy of Opdivo® and Rubraca® with BMS and Clovis

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced that it has entered into the clinical collaboration agreement with Bristol-Myers Squibb Company (NYSE: BMY, "BMS") and Clovis Oncology, Inc. (NASDAQ: CLVS, "Clovis") to evaluate the combination therapy of ONO/BMS's Opdivo® (nivolumab, "Opdivo"), a human anti-human PD-1 (programmed cell death-1) monoclonal antibody, and Clovis' Rubraca® (rucaparib, "Rubraca"), an inhibitor of poly (ADP-ribose) polymerase (PARP) in multiple tumor types including ovarian cancer, breast cancer and prostate cancer in Japan, South Korea and Taiwan.

In accordance with this agreement, ONO has rights to enter into clinical studies, in Japan, South Korea and Taiwan, which are planned or ongoing to evaluate the efficacy and safety of combination therapy of Opdivo and Rubraca outside these countries under the collaboration between BMS and Clovis. Currently, Clovis is conducting a Phase 3 study for the treatment of ovarian cancer and planning to conduct a Phase 2 study for ovarian and bladder cancers. BMS is conducting a Phase 2 study for prostate cancer and planning to conduct a Phase 3 study for triple negative breast cancer.

Development status of Opdivo and Rubraca in ovarian cancer and prostate cancer

ONO and BMS are conducting Phase 3 study in patients with ovarian cancer with Opdivo in Japan, and Phase 2 study with Opdivo in combination with other drugs for prostate cancer in the US and Europe.

Clovis has received approvals for Rubraca in multiple recurrent ovarian cancer settings in the US and Europe, and is conducting both monotherapy and combination development programs in several solid tumor types, including ovarian, prostate and bladder cancers. In Japan, a Phase 1 is ongoing for solid tumors.

About Ovarian Cancer

Ovarian cancer is the seventh most common cancer in women worldwide, with about 240,000 new patients diagnosed in 2012. In Japan, there is a tendency in increasing the number of patients with ovarian cancer with more than 10,000 expected patients and about 4,800 deaths in 2017*. There are often no specific initial symptoms in ovarian cancer, and in an estimated 80 to 85% of ovarian cancer patients, the cancer has spread to other parts of the body before a person is diagnosed and can be treated.

About Prostate Cancer

Prostate cancer is the second most frequently diagnosed cancer in men, with 1.1 million new patients diagnosed worldwide in 2012. In Japan, there is an increasing tendency in the number of prostate cancer patients with about 86,100 expected patients in 2017*, and prostate cancer is the third most common cancer in men, following gastric cancer and lung cancer. Unlike many early-stage

prostate cancers that need normal levels of testosterone to grow, castration-resistant prostate cancer (CRPC) continues to grow even when the amount of testosterone in the body is reduced to castrate levels. CRPC patients have a very high likelihood of having or developing metastases, meaning the cancer has spread to other areas of the body. While the 5-year survival rate for most stages of prostate cancer is almost 100%; the 5-year survival rate for prostate cancer that has spread to distant lymph nodes, bones, or other organs is approximately 29%.

About Triple-Negative Breast Cancer

Triple-negative breast cancer is a type of breast cancer where the cancer cells tested negative for expression of estrogen receptors, progesterone receptors and HER-2 receptors. Since the tumor cells lack the necessary receptors, common treatments like hormone therapy and drugs that target HER-2 are ineffective. This remains a disease with significant unmet medical need. Therefore, the development of new medicines is necessary to advance the treatment of triple-negative breast cancer.

Breast cancer is the most frequently diagnosed cancer in women worldwide with nearly 1.7 million new patients diagnosed in 2012, accounting for 25% of all new cancer patients in women. In Japan, breast cancer is the most frequently diagnosed cancer in women with about 89,000 expected patients and about14,000 deaths in 2017*. More than one out of every 10 breast cancers are found to be triple-negative, meaning the cancer does not have the biomarkers that predict response to hormonal therapy or therapies that target HER2 receptors. Triple negative tumors are often aggressive and have a poorer prognosis compared to hormone receptor positive breast cancers.

* : Projected Cancer Statistics, 2017, Center for Cancer Control and Information Services, National Cancer Center https://ganjoho.jp/en/public/statistics/short_pred.html

About Opdivo

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumor immune response by blocking the interaction between PD-1 and its ligands.

In Japan, ONO launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, ONO received an approval for additional indication of unresectable, advanced or recurrent non-small cell lung cancer in December 2015, unresectable or metastatic renal cell cancer in August 2016, relapsed or refractory classical Hodgkin lymphoma in December 2016, recurrent or metastatic head and neck cancer in March 2017 and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017, and unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma, etc. in August 2018. In addition, ONO is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, biliary tract cancer, etc.

In abroad, BMS has a robust clinical development program for Opdivo monotherapy and in combination with other Immuno-Oncology and non-Immuno-Oncology therapies across more than 350 clinical trials. BMS is studying Opdivo in approximately 50 types of cancer, across solid tumors and hematologic malignancies, and is utilizing its translational medicine capabilities to tailor approaches with the goal of providing maximal benefit for individual patients.

Opdivo is currently approved in more than 60 countries, including Japan, South Korea, Taiwan, the US and European Union.

About the ONO and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement made between ONO and Bristol-Myers Squibb (BMS), 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 Opdivo except the US at the time. In July 2014, ONO and BMS further expanded their strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agent and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

About Rubraca®

Rubraca is an oral, small molecule inhibitor of PARP-1, PARP-2 and PARP-3 being developed in ovarian cancer as well as several additional solid tumor indications. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder cancers. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rubraca is also approved in the United States for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca.

Rubraca is an unlicensed medical product outside of the US and EU.

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