February 3, 2022

ONO and Bristol Myers Squibb Sign Outsourcing Agreement with PRiME-R on Clinical Research of Opdivo® in Patients with Gastric Cancer, utilizing CyberOncology® in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") and Bristol-Myers Squibb K.K. (Tokyo, Japan; President, Jean-Christophe Barland) today announced that the companies have signed an outsourcing agreement with Prime Research Institute for Medical RWD, Inc. (Kyoto, Japan; "PRiME-R") on an industry-sponsored, large-scale, multi-institutional clinical research in patients with gastric cancer treated with Opdivo® (generic name: nivolumab) in combination with chemotherapy. The study will be conducted utilizing the PRiME-R's data input support system "CyberOncology®" that standardizes, structures, manages and integrates real-world data* in daily cancer clinical practice.

* Real-world data: Medical information such as electronic medical chart data, drug information and disease registration data obtained from various medical sources.

This clinical (observational) research using CyberOncology® is designed to investigate the efficacy, safety and actual clinical practice of Opdivo in combination with chemotherapy in patients with advanced or recurrent gastric cancer who have previously untreated in actual clinical settings. It will be conducted at about 30 medical institutions across the country. By incorporating the advanced CyberOncology® in this observational research, the companies aim to reduce the input load at medical institutions, improve the accuracy of clinical research data and accelerate data aggregation and analysis. This is the first industry-sponsored, large-scale, multi-institutional clinical research using CyberOncology® in Japan.

Dr. Kei Muro, Director of the Department of Clinical Oncology/Deputy Director of Aichi Cancer Center Hospital, and an advisor of this clinical research, said, "First-line treatment of gastric cancer with Opdivo in combination with chemotherapy is currently being practiced in many gastric cancer patients as a new standard treatment. The Phase 3 study that led to its approval is uniform, so to speak, limited patient population group evidence. The safety and efficacy data to be obtained from the real world data of this observational research will include information on heterogeneous patient populations in actual clinical practice, and we expect that it will contribute to the creation of valuable insights that can inform the true value of this combination therapy and important points to note for treatment in actual clinical practice."

Dr. Manabu Muto, Professor, Therapeutic Oncology, the Graduate School of Medicine and Faculty of Medicine Kyoto University, and also an advisor of this clinical research, said, "I am very pleased to be able to commence this initiative to collect information on immuno-oncology therapy for gastric cancer, the second most common cancer in Japan, using CyberOncology® technology. If the data to be collected in this research can visualize the safety and efficacy of immuno-oncology therapy in the treatment of gastric cancer in a manner suitable for actual clinical practice, I expect that it will lead to the implementation of safer and more effective cancer therapies and new developments."

CyberOncology® is a data input support system developed by PRiME-R that standardizes, structures, manages and integrates real-world data in daily clinical practice. In the past, clinical research data had to be manually re-entered into clinical study-specific case report systems separately from the data accumulated in electronic medical records at medical institutions, which required a double entry process. CyberOncology® will help to reduce the burden of inputting data into electronic medical

records at medical institutions and increase the accuracy of data that may be used for clinical research. In addition, part of the structured data, such as laboratory test and drug administration information, can be automatically extracted from electronic medical records and used as research data, enabling more efficient usage. Furthermore, CyberOncology® supports the use of multiple types of electronic medical records, and even if the format of electronic medical records held at medical institutions varies, their data can be extracted centrally. Since all necessary real world data can be integrated in a short period of time, it is expected that the accuracy and speed of this large-scale, multi-institutional clinical research will be enhanced.

ONO and Bristol-Myers Squibb will continue to actively pursue innovative drug development and clinical research with advanced technology to provide safe and highly effective treatment options to cancer patients.

About gastric cancer

It is estimated that about 138,000 new cases are diagnosed with gastric cancer per year in Japan (about 1,089,000 cases worldwide) and approximately 46,000 deaths (about 768,000 worldwide) per year resulting from this disease.[1]

[1]*These figures were sourced from (a) Globocan 2020: Stomach Cancer, Japan, World Health Organization at: https://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf and (b) Globocan 2020: Stomach Cancer, World, World Health Organization at: https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf*

Regarding the gastric cancer indication of Opdivo, it was approved in September 2017 for the treatment of “unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy” (third-line treatment), and in November 2021 “unresectable advanced or recurrent gastric cancer” in combination with chemotherapy (first-line treatment) in Japan.

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 July 2014, ONO received approval in Japan of Opdivo, which harnesses the body’s own immune system to fight cancer, for the treatment of unresectable melanoma, and launched Opdivo in September 2014. After that, Opdivo has become an important treatment option across multiple cancers. Opdivo is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, China, the US and European Union.

About ONO and Bristol-Myers Squibb’s Collaboration

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

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