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Ono Pharmaceutical Co., Ltd.
Bristol-Myers Squibb K.K.

Japanese Translation of Plain Language Summary, Summarizing Literature on Clinical Trial Results of Opdivo in Easy-to-Understand Description Using Plain Language Published in Future Oncology

- Starting support for Japanese translation of plain language summary to patients and general public -

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President and CEO: Gyo Sagara) and Bristol-Myers Squibb K.K. (Tokyo, Japan; President: Steve Sugino) announced that the Japanese translation of the plain language summaries of Publication ("PLS") of the following 3 clinical trial results of anti-PD-1 antibody, "Opdivo® (generic name: nivolumab) Intravenous Infusion" published in Future Oncology, a scientific journal that publishes scientific findings on cancer research and treatment has been posted in the same journal, Future Oncology:

1) Plain language summary of the CheckMate 816 study results: nivolumab plus chemotherapy given before surgery for non–small-cell lung cancer[1]
2) A plain language summary of the CheckMate 649 study: nivolumab in combination with chemotherapy compared to chemotherapy alone for untreated advanced or metastatic cancer of the stomach or esophagus[2]
3) Treatment of muscle-invasive urothelial cancer with nivolumab (CheckMate 274 study): a plain language summary[3]

The PLS are summaries of clinical trial results describing in plain language so that they can be easily understood not only for experts such as scientists and healthcare professionals, but also for broader general public, including patients participated in clinical trials and their families. In association with the increasing number of international journals that accept PLS, the number of PLS has been increasing globally in recent years. Regarding the Japanese translation of the PLS, both Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb K.K. have started to provide supports for preparation of the Japanese translation so that the Japanese general public can easily understand the contents.

"The medical literature reporting the results of clinical trials are technical in nature and very difficult to understand for the general public, including patients participating in clinical trials," said Dr. Tetsuya Mitsudomi, Specially-appointed Professor, Kindai University Hospital and Director of the Global Research Alliance Center (co-author of the PLS of the CheckMate 816 study). "I hope that patients will be able to better understand the pros and cons of the treatment options and proactively choose the treatment by reading the Japanese translation of PLS which is written in easy-to-understand language. I also expect that the Japanese translation of PLS may be utilized in clinical practice as explanatory materials to patients in the future."

"It is very meaningful for pharmaceutical companies to disclose clinical trial results in a transparent and easy-to-understand format. As the figures used are well organized to be easy to understand, I believe that they will be useful as a reference not only for patients, but for healthcare professionals," said Dr. Kensei Yamaguchi, Deputy Hospital Director, and Department Director of Gastroenterological Chemotherapy, the Cancer Institute Hospital of Japanese Foundation for Cancer Research (co-author of the PLS of the CheckMate 649 study). "In the field of gastric cancer, the "Gastric Cancer Treatment Guidelines for patients" was revised in March 2023 for the first time in 19 years. I hope that increased awareness and understanding of the PLS and guidelines will help patients choose the treatment options."

"For patients who are native speakers of Japanese and want to learn more about their own illness, medical papers written in English that use a lot of technical terms are difficult to read. I believe that that this is one of the unmet needs in Japanese medical care," said Dr. Yoshihiko Tomita, Professor, Division of Urology / Molecular Oncology, Nigata University Graduate School of Medical and Dental Sciences (co-author of the PLS of the CheckMate 274 study). "I believe that the wider availability of the Japanese translation of the PLS will lead to the provision of safe and secure patient-oriented medical care. I am sure that not only the patient but also their families will be very worried and anxious, but am confident that the Japanese translation of the PLS will help patients themselves and their families understand the clinical trial results."

Starting with Japanese translation of the results of the three clinical trials on Opdivo published in Future Oncology, Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb K.K. will provide further supports for the Japanese translation of the PLS on pivotal Phase III clinical trials to be published in international journals.

About the ONO and Bristol Myers Squibb Collaboration

In 2011, through a collaboration agreement with 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 the companies' 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.

Reference:

1. Forde P, Plain language summary of the CheckMate 816 study results: nivolumab plus chemotherapy given before surgery for non–small-cell lung cancer. Future Oncology https://www.futuremedicine.com/doi/10.2217/fon-2023-0007
2. Janjigian Y, A plain language summary of the CheckMate 649 study: nivolumab in combination with chemotherapy compared to chemotherapy alone for untreated advanced or metastatic cancer of the stomach or esophagus. Future Oncology https://www.futuremedicine.com/doi/10.2217/fon-2022-1149
3. Bajorin D, Treatment of muscle-invasive urothelial cancer with nivolumab (CheckMate 274 study): a plain language summary. Future Oncology https://www.futuremedicine.com/doi/10.2217/fon-2022-1294

Contact:
Ono Pharmaceutical Co., Ltd.
Corporate Communications
public_relations@ono-pharma.com