ONO PHARMA

Press Release

Ono Pharma Submits a Supplemental Application in Japan to Expand the Use of OPDIVO for the Treatment of Unresectable Anaplastic Thyroid Cancer

- Supplemental application was submitted in Japan for a partial change in the manufacturing and marketing approval of OPDIVO for the indication of unresectable anaplastic thyroid cancer
- In an investigator-initiated trial evaluating combination therapy with OPDIVO and Lenvima, the primary endpoint, objective response rate, was met
- The safety profile of this combination therapy was confirmed to be manageable

Osaka, Japan, June 11, 2026 - Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; "Ono") today announced that it submitted a supplemental application of OPDIVO® Intravenous Infusion (generic name: nivolumab; "OPDIVO") , a fully human PD-1 monoclonal antibody in Japan, to expand its use for the treatment of unresectable anaplastic thyroid cancer, for a partial change in approved items of the manufacturing and marketing approval.

This application is based on the results of the Japanese phase 2 investigator-initiated trial (the NAVIGATION study, YCU18001), by the National Cancer Center Hospital East, which evaluated combination therapy in patients with unresectable anaplastic thyroid cancer with OPDIVO and Lenvima® (generic name: lenvatinib mesylate; "Lenvima"), a receptor tyrosine kinase inhibitor discovered by Eisai Co., Ltd., that inhibits kinases implicated in pathogenic angiogenesis and tumor growth. The results of this study showed an objective response rate of 47.6% (95% confidence interval, 33.4 to 62.3%), thus meeting the primary endpoint. In terms of safety, adverse events were manageable with appropriate measures.[1]

Anaplastic thyroid cancer is a type of thyroid cancer and an epithelial malignant tumor characterized by marked architectural and cytological atypia.[2, 3] Although it is a rare cancer type, with the number of patients in Japan estimated to be approximately 170 to 1,640, the prognosis is poor.[4, 5] While several drugs have been approved for the treatment of unresectable anaplastic thyroid cancer, treatment options remain limited. Standard therapy for anaplastic thyroid cancer has yet to be established, and there is a high need for developing new treatment approaches.

OPDIVO was designated as an orphan drug for the indication of unresectable anaplastic thyroid cancer on May 18, 2026, and is accepted for priority review by the Ministry of Health, Labour and Welfare (MHLW).

About NAVIGATION Study

This study is a multicenter, open-label, single-arm phase 2 clinical study initiated by investigators to evaluate the tolerability, safety, and efficacy of OPDIVO in combination with Lenvima in patients with unresectable anaplastic thyroid cancer. Patients received 240 mg of OPDIVO every two weeks and 24 mg of Lenvima once daily. The primary efficacy endpoint is objective response rate (central assessment). The secondary endpoints included objective response rate (investigator's assessment), disease control rate, progression-free survival, and overall survival.

About OPDIVO

OPDIVO is a programmed cell 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. By harnessing the body's own immune system to fight cancer, OPDIVO has become an important treatment option across multiple cancers since the approval for the treatment of melanoma in Japan in July 2014. OPDIVO is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, China, the US, and European Union.

In Japan, Ono launched OPDIVO in September 2014 for the treatment of unresectable malignant melanoma. Thereafter, additional indications were approved: unresectable advanced or recurrent non-small cell lung cancer in December 2015; unresectable or metastatic renal cell carcinoma in August 2016; relapsed or refractory classical Hodgkin lymphoma in December 2016; recurrent or metastatic head and neck cancer in March 2017; unresectable advanced or recurrent gastric cancer that progressed after chemotherapy in September 2017; unresectable advanced or recurrent malignant pleural mesothelioma that progressed after chemotherapy in August 2018; MSI-High colorectal cancer and unresectable advanced or recurrent esophageal cancer that progressed after chemotherapy in February 2020; cancer of unknown primary in December 2021; adjuvant therapy for urothelial carcinoma in March 2022; malignant mesothelioma (excluding malignant pleural mesothelioma) in November 2023; unresectable advanced or recurrent epithelial skin malignancies in February 2024; unresectable hepatocellular carcinoma in June 2025.

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.

References:

1. Tahara M, Kiyota N, Saijo K, et al. Nivolumab plus lenvatinib for unresectable anaplastic thyroid cancer: Results of the phase 2 NAVIGATION study. Proceedings of the ASCO Annual Meeting. 2026; Rapid oral presentation. Abstract 6021.
2. Official Journal of the Japan Association of Endocrine Surgery. 2024;41(Suppl 2).
3. Japanese General Rules for the Description of Thyroid Cancer (The 9th Edition). 2023.
4. Patient Survey 2023, Ministry of Health, Labour and Welfare.
5. CANCER STATISTICS IN JAPAN 2026.

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