ONO PHARMACEUTICAL CO.,LTD.

May 10, 2019

Certain Media Coverage relating to Opdivo Reported on May 9

Ono Pharmaceutical Co., Ltd. (Osaka, Japan: "ONO") announced as follows the situation of the additional description on "pituitary dysfunction" to the item of "Clinically significant adverse reactions" of the package insert for Opdivo, an anti-tumor agent, which was reported on May 9 by Kyodo News, the leading news agency in Japan:

According to the notification of the Director of the Safety Division, Pharmaceutical Safety and Environmental Health Bureau (PSEHB) of the Ministry of Health, Labour and Welfare, based on the accumulation of the adverse drug reaction cases reported from the domestic post-marketing setting, "pituitary dysfunction" was additionally described in the item of "Clinically significant adverse reactions" of the Opdivo package insert in order to draw the attention of healthcare professionals, etc. on May 9, 2019. (ONO has drawn their attentions to the event so far by describing the events of "hypopituitarism, hypophysitis and decreased blood corticotrophin" in the item of "Other adverse reactions".)

Pituitary dysfunction (CTCAE Grade 4 or more or severe case with cortisol less than 4.0 μg/dL) suspected to have a causal relationship with Opdivo has been reported in 11 cases (3 cases in melanoma and 8 cases in non-small cell lung cancer: NSCLC) with one death case in NSCLC as of November 7, 2018.

Although the mechanism of Opdivo causing the event is not clear, ONO considers that the possibility that the administration of Opdivo may cause the event cannot be ruled out due to its effect of enhancing the immune response.

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