ONO PHARMACEUTICAL CO.,LTD.

April 13, 2020

U.S. FDA Approves BRAFTOVI® (Encorafenib) in Combination with Cetuximab for the Treatment of $BRAF^{V600E}$-mutant Metastatic Colorectal Cancer (CRC) after Prior Therapy

This information is intended to notify the press release issued on April 8, 2020 (ET) by Pfizer Inc. Please click https://investors.pfizer.com/investor-news/default.aspx for the original press release.

(1st paragraph of the press release)

NEW YORK, N.Y., April 8, 2020 – Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has approved BRAFTOVI® (encorafenib) in combination with cetuximab (marketed as ERBITUX®) for the treatment of adult patients with metastatic colorectal cancer (CRC) with a $BRAF^{V600E}$ mutation, as detected by an FDA-approved test, after prior therapy.[1] The approval is based on results from the BEACON CRC trial, the only Phase 3 trial to specifically study patients with previously treated metastatic CRC with a $BRAF^{V600E}$ mutation.

About the Ono and Pfizer Inc. Collaboration

In May 2017, Ono Pharmaceutical Co., Ltd. ("ONO") entered into the license agreement with Array BioPharma Inc. (currently, a subsidiary of Pfizer Inc.) regarding BRAFTOVI® (encorafenib), a BRAF inhibitor and MEKTOVI® (binimetinib), a MEK inhibitor to receive rights to develop and commercialize both products in Japan and South Korea.

About the Development Status of BRAFTOVI® and MEKTOVI®

In January 2019, ONO received the manufacturing and marketing approvals for BRAFTOVI® and MEKTOVI® in combination therapy and launched them for the indication of unresectable BRAF-mutant melanoma in Japan in February 2019. In March 2020, ONO submitted a supplemental application for both products for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer, in combination therapy with cetuximab, an anti-human EGFR monoclonal antibody.

The products are currently in Phase 3 clinical trial for the treatment of patients with BRAF-mutant melanoma (COLUMBUS study), Phase 3 for previously treated BRAF-mutant colorectal cancer (BEACON CRC study), and Phase 2 for previously untreated BRAF-mutant colorectal cancer (ANCHOR study).

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