

December 19, 2019

U.S. FDA Accepts and Grants Priority Review to sNDA for BRAFTOVI® (encorafenib) in Combination with ERBITUX® (cetuximab) (Braftovi Doublet) for the Treatment of BRAF^{V600E}-Mutant Metastatic Colorectal Cancer After Prior Therapy

This information is intended to notify the press release issued on December 18, 2019 (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., December 18, 2019 - Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has accepted and granted priority review to the Company's supplemental New Drug Application (sNDA) for BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab) (BRAFTOVI Doublet) based on results from the Phase 3 BEACON CRC trial, which evaluated the efficacy and safety of BRAFTOVI in combination with ERBITUX with or without MEKTOVI® (binimetinib) in patients with advanced BRAF^{V600E}-mutant metastatic colorectal cancer (mCRC), following one or two lines of therapy.

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 and received 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® and launched them for the indication of unresectable BRAF-mutant melanoma in Japan in February 2019. The products are currently in Phase 3 clinical trial for the treatment of patients with BRAF-mutant melanoma (COLUMBUS study), Phase 3 for BRAF-mutant colorectal cancer (BEACON CRC study) as a combination therapy, and Phase 2 for previously untreated BRAF-mutant colorectal cancer in a combination therapy with ERBITUX (cetuximab) (ANCHOR study).

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