ONO PHARMACEUTICAL CO.,LTD.

June 28, 2018

Array Biopharma Announces FDA Approval of Braftovi™ (Encorafenib) in Combination with Mektovi® (Binimetinib)

Boulder, Colo., (June 27, 2018) – Array BioPharma Inc. (NASDAQ: ARRY) announced that the U.S. Food and Drug Administration (FDA) has approved BRAFTOVI™ capsules in combination with MEKTOVI® tablets for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation, as detected by an FDA-approved test. BRAFTOVI is not indicated for the treatment of patients with wild-type BRAF melanoma.

The approval of BRAFTOVI + MEKTOVI is based on results from the Phase 3 COLUMBUS trial, which demonstrated the combination doubled median progression-free survival (mPFS) compared to vemurafenib, alone (14.9 months versus 7.3 months, respectively [HR (0.54), (95% CI 0.41-0.71), p<0.0001]). Only 5% of patients who received BRAFTOVI + MEKTOVI discontinued treatment due to adverse reactions.

The most common adverse reactions (≥25%) in patients receiving BRAFTOVI + MEKTOVI were fatigue, nausea, diarrhea, vomiting, abdominal pain, and arthralgia.

Ono Pharmaceutical Co., Ltd. (“ONO”) entered into the license agreement with Array BioPharma Inc. regarding encorafenib, a BRAF inhibitor and binimetinib, a MEK inhibitor in May 2017 and received rights to develop and commercialize both products in Japan and South Korea. In April 2018, ONO submitted applications for the manufacturing and marketing approval of both compounds in Japan for the indication of unresectable BRAF-mutant melanoma. Encorafenib and binimetinib are currently in two global Phase 3 clinical trials for the treatment of patients with BRAF-mutant melanoma (COLUMBUS study) and BRAF-mutant colorectal cancer (BEACON CRC study) as a combination therapy.

Please click here for the press release distributed by Array BioPharma Inc.

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