ONO PHARMACEUTICAL CO.,LTD.

July 30, 2018

BRAFTOVI™ (encorafenib) + MEKTOVI® (binimetinib) Receives Positive CHMP Opinion for Advanced BRAF-mutant Melanoma

Boulder, Colo., (July 27, 2018) – Array BioPharma Inc. (NASDAQ: ARRY) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of BRAFTOVI™ in combination with MEKTOVI® for the treatment of adult patients with unresectable or metastatic melanoma with a $BRAF^{V600}$ mutation. The CHMP recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The final EC decision, expected by the end of September, will be applicable to all 28 EU member states, as well as Liechtenstein, Iceland and Norway.

The positive CHMP opinion is based on results from the Phase 3 COLUMBUS trial, which demonstrated that the combination BRAFTOVI + MEKTOVI achieved a median progression-free survival (mPFS) of nearly 15 months [14.9 months versus vemurafenib monotherapy at 7.3 months; hazard ratio (HR) 0.54 (95% CI, 0.41–0.71), p<0.0001].

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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