ONO PHARMACEUTICAL CO.,LTD.

September 14, 2017

Array BioPharma Announces FDA Acceptance for Review of Binimetinib and Encorafenib New Drug Applications for Patients with Advanced BRAF-mutant Melanoma

Boulder, Colo., (September 12, 2017) – Array BioPharma (Nasdaq: ARRY) announced that the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Applications (NDAs) to support use of the combination of binimetinib 45 mg twice daily and encorafenib 450 mg once daily (COMBO450) for the treatment of patients with BRAF-mutant advanced, unresectable or metastatic melanoma. The FDA set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 30, 2018 for both applications. In addition, the FDA informed Array that based on their preliminary review of the applications they have not identified any potential review issues, and that they are not currently planning to hold an advisory committee meeting to discuss these NDAs. Array completed its NDA submissions at the end of June 2017 based on findings from the pivotal Phase 3 COLUMBUS trial.

Ono Pharmaceutical Co., Ltd. (“ONO”) entered into the license agreement with Array BioPharma Inc. regarding binimetinib, a MEK inhibitor and encorafenib, a BRAF inhibitor in May 2017 and received rights to develop and commercialize both products in Japan and South Korea.

Binimetinib and encorafenib are currently in two global Phase 3 clinical trials for the treatment of patients with BRAF-mutant melanoma (COLUMBUS study including Japan and South Korea) and BRAF-mutant colorectal cancer (BEACON CRC study including South Korea) as a combination therapy.

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

ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
Public_relations@ono.co.jp