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Array BioPharma Receives FDA Breakthrough Therapy Designation for BRAFTOVI™ in Combination with MEKTOVI® and Cetuximab for BRAF^{V600E}-mutant Metastatic Colorectal Cancer

The following is the press release (1st paragraph) issued by Array Biopharma. Please click http://www.arraybiopharma.com/ for the original press release distributed by Array.

(1st paragraph of the press release)

BOULDER, Colo., Aug. 7, 2018 /PRNewswire/ -- Array BioPharma Inc. (NASDAQ: ARRY) today announced it has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for encorafenib (BRAFTOVITM), in combination with binimetinib (MEKTOVI®) and cetuximab for the treatment of patients with BRAF^{V600E}-mutant metastatic colorectal cancer (mCRC) as detected by an FDA-approved test, after failure of one to two prior lines of therapy for metastatic disease. BRAF^{V600E}-mutant mCRC patients have a mortality risk more than double that of mCRC patients without the mutation, and currently there are no therapies specifically approved for this high unmet need population.

About the Ono Pharmaceutical and Array BioPharma Collaboration

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 for 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.

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