

# Array BioPharma to Present Updated Phase 3 BEACON CRC Safety Lead-In Results of the Combination of Encorafenib, Binimetinib and Cetuximab in BRAF-Mutant Colorectal Cancer at the 2018 Gastrointestinal Cancers Symposium

January 16, 2018

- January 16: Abstract contains previously presented safety and clinical activity data, as well as new data on tumor markers -
- January 20: Presentation to include updated overall response rate (ORR), duration of response and safety, as well as new data on median progression free survival (mPFS) -

BOULDER, Colo., Jan. 16, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) today announced the upcoming presentation of updated safety results and clinical activity from the safety lead-in of the Phase 3 BEACON CRC trial evaluating the triplet combination of encorafenib, a BRAF inhibitor, binimetinib, a MEK inhibitor and cetuximab, an anti-EGFR antibody, in patients with *BRAF*-mutant colorectal cancer (CRC). These data will be presented at the 2018 Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco, California.

## **BEACON CRC SAFETY LEAD-IN**

Title: Abstract #627: BEACON CRC Study Safety Lead-in (SLI) in Patients With BRAFV600E Metastatic Colorectal Cancer (mCRC): Efficacy

and Tumor Markers

Presenter: Eric Van Cutsem, M.D., University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium

Date: Saturday, January 20

Times: 7:00 am - 7:55 am PT and 12:30 pm - 2:00 pm PT

Updated data on the safety and tolerability profile of the triplet combination and measures of efficacy, including mPFS, ORR, duration of response, as well as tumor marker data, will be available as part of the presentation on January 20. The presentation will be available as a PDF from the Publications section of the Array website starting January 20.

Array's BEACON CRC Phase 3 trial safety lead-in abstract published on January 16 contains previously presented safety and clinical activity data, as well as new data on changes in tumor markers.

#### **About Encorafenib and Binimetinib**

BRAF and MEK are key protein kinases in the MAPK signaling pathway (RAS-RAF-MEK-ERK). Research has shown this pathway regulates several key cellular activities including proliferation, differentiation, survival and angiogenesis. Inappropriate activation of proteins in this pathway has been shown to occur in many cancers, including melanoma and colorectal cancer. Encorafenib is a late-stage small molecule BRAF inhibitor and binimetinib is a late-stage small molecule MEK inhibitor, both of which target key enzymes in this pathway. Encorafenib and binimetinib are being studied in clinical trials in advanced cancer patients, including the Phase 3 BEACON CRC trial and the Phase 3 COLUMBUS trial.

The U.S. Food and Drug Administration (FDA) is currently reviewing the New Drug Applications (NDAs) to support use of the combination of encorafenib and binimetinib 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 European Medicines Agency (EMA) is reviewing the Marketing Authorization Applications for encorafenib and binimetininb.

Encorafenib and binimetinib are investigational medicines and are not currently approved in any country.

Array BioPharma has exclusive rights to encorafenib and binimetinib in the U.S. and Canada. Array has granted Ono Pharmaceutical exclusive rights to commercialize both products in Japan and South Korea and Pierre Fabre exclusive rights to commercialize both products in all other countries, including Europe, Asia and Latin America. The BEACON CRC trial is being conducted with support from Pierre Fabre and Merck KGaA, Darmstadt, Germany (support is for sites outside of North America).

### **About Array BioPharma**

Array BioPharma Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer. Nine registration studies are currently advancing related to seven Array-owned or partnered drugs: encorafenib (LGX818), binimetinib (MEK162), selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Cascadian Therapeutics).

## Array BioPharma Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about the future development plans of encorafenib and binimetinib; expectations regarding approval of encorafenib and binimetinib for *BRAF*-mutant melanoma; expectations that events will occur that will result in greater value for Array; and the potential for the results of current and further clinical trials to support regulatory approval or the marketing success of encorafenib and binimetinib. Specifically, there is no assurance that results from the BEACON CRC trial will satisfy the requirements of regulatory authorities necessary to file an application for marketing approval, or that if such application is accepted, that it will be approved. These statements involve significant risks and uncertainties, including those discussed in our most recent annual report filed on Form 10-K, in our quarterly reports filed on Form 10-Q, and in other reports filed by Array with the Securities and Exchange Commission. Because these statements reflect our current expectations concerning future events, our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors. These factors include, but are not limited to, the determination by the FDA, EMA or other regulatory agencies that results from clinical trials are not sufficient to support registration or marketing approval of encorafenib and binimetinib; our ability to effectively and timely conduct clinical trials in light of increasing costs and difficulties in locating appropriate trial sites and in enrolling patients who meet the criteria for certain clinical trials; risks associated with our dependence on third-party service providers

to successfully conduct clinical trials and to manufacture drug substance and product within and outside the United States; our ability to grow and successfully develop commercialization capabilities; our ability to achieve and maintain profitability and maintain sufficient cash resources; and our ability to attract and retain experienced scientists and management. We are providing this information as of January 16, 2018. We undertake no duty to update any forward-looking statements to reflect the occurrence of events or circumstances after the date of such statements or of anticipated or unanticipated events that alter any assumptions underlying such statements.

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