



## Array BioPharma Provides NEMO Update

March 19, 2017

- **NRAS-mutant melanoma NDA withdrawn based on thorough discussions with FDA and following late cycle review meeting -**
- **Ongoing binimetinib clinical studies will continue; withdrawal will not impact planned COLUMBUS NDA submission of binimetinib, in combination with encorafenib, for BRAF-mutant melanoma expected in mid-2017 -**

BOULDER, Colo., March 19, 2017 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) today announced that it has withdrawn from the U.S. Food and Drug Administration's (FDA) Division of Oncology Products 2 its new drug application (NDA) for binimetinib monotherapy for the treatment of *NRAS*-mutant melanoma, a rare, mutationally-driven subset of skin cancer.

This action was based on thorough discussions and communications with the FDA, including exploration of various paths to approval, and followed the late cycle review meeting held with the FDA on Friday, March 17, 2017. Based on feedback from the agency, Array concluded that the clinical benefit demonstrated in the Phase 3 NEMO clinical trial would not be found sufficient to support approval of the *NRAS*-mutant melanoma NDA.

Ongoing clinical trials for binimetinib will continue. This action will not impact the planned Phase 3 COLUMBUS trial NDA of binimetinib, in combination with encorafenib, for the treatment of *BRAF*-mutant melanoma, which remains on track for mid-2017.

### About *NRAS*-Mutant Melanoma

Of the estimated 10,000 annual cases of metastatic melanoma in the United States, activating *NRAS* mutations are present in approximately 20 percent of these patients. The presence of an *NRAS* mutation is a poor prognostic indicator for these patients, and treatment options for this population remain limited beyond immunotherapy.

### 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. Seven registration studies are currently advancing related to six Array-owned or partnered drugs: binimetinib (MEK162), encorafenib (LGX818), selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Cascadian Therapeutics).

### 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 timing of the announcement of the results of clinical trials for our proprietary and our partnered programs, the timing of the completion or initiation of further development of our wholly-owned and our partnered programs, including the timing of regulatory filings, expectations that events will occur that will result in greater value for Array, the potential for the results of ongoing preclinical and clinical trials to support regulatory approval or the marketing success of a drug candidate, our ability to partner our proprietary drug candidates for up-front fees, milestone and/or royalty payments, our future plans to progress and develop our proprietary programs, our future capital requirements and the plans of our collaborators to progress and develop programs we have licensed to them, and our plans to build a late-stage development company. 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, our ability to continue to fund and successfully progress internal research and development efforts and to create effective, commercially-viable drugs; risks relating to the regulatory approval process for our drug candidates, which may not result in approval for our drug candidates, cause delays in development or require that we expend more resources to obtain approval than expected; risks associated with our dependence on our collaborators for the clinical development and commercialization of our out-licensed drug candidates; the ability of our collaborators and of Array to meet objectives tied to milestones and royalties; 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 within and outside the United States; our ability to achieve and maintain profitability and maintain sufficient cash resources; the extent to which the pharmaceutical and biotechnology industries are willing to in-license drug candidates for their product pipelines and to collaborate with and fund third parties on their drug discovery activities; our ability to out-license our proprietary candidates on favorable terms; and our ability to attract and retain experienced scientists and management. We are providing this information as of March 19, 2017. 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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