Combination of Encorafenib, Binimetinib and Cetuximab Demonstrated an 8 Month Median Progression-Free Survival in BRAF-Mutant Colorectal Cancer in Updated Safety Lead-In Results from BEACON Phase 3 Trial

January 20, 2018

-- Median PFS of 8.0 months at time of analysis --
-- 48% confirmed ORR, including 3 complete responses --
-- Data presented at the ASCO 2018 Gastrointestinal Cancers Symposium --

BOULDER, Colo. and CASTRES, France, Jan. 20, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) and Pierre Fabre today announced updated results from the 30 patient 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 metastatic colorectal cancer (CRC) whose disease has progressed after one or two prior regimens. The data were presented at the ASCO 2018 Gastrointestinal Cancers Symposium in San Francisco, California.

In patients with the $BRAF^{V600E}$ mutation, the estimated median progression-free survival (mPFS) at the time of analysis was 8 months. The confirmed overall response rate (ORR)* in patients with the $BRAF^{V600E}$ mutation was 48%, and 3 patients achieved complete responses (CR). Further, the ORR was 62% in the 16 patients (10/16) who received only one prior line of therapy. These data represent substantial improvements compared to several separate historical published standard of care benchmarks for this population.

"We are very excited about these safety lead-in results, which show both an unprecedented progression-free survival and overall response rate in patients with $BRAF^{V600}$-mutant colorectal cancer," said Scott Kopetz, M.D., Ph.D., FACP, Associate Professor, Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. "To put these data in context, the observed median progression-free survival of 8 months exceeds historical benchmarks of approximately 2 months for median progression-free survival, and 4 to 6 months for median overall survival, with current standards of care in this patient population. These results demonstrate the potential of the triplet combination to benefit this population of patients who currently have very limited effective treatment options."

In the safety lead-in, the triplet combination was generally well-tolerated. Two patients discontinued treatment due to adverse events (AEs) with only one of these considered related to treatment. The most common grade 3 or 4 AEs seen in at least 10% of patients were fatigue (4/30), urinary tract infection (3/30), increased aspartate aminotransferase (AST; 3/30) and increased blood creatine kinase (CK; 3/30).

All patients with elevated baseline levels of the tumor markers CEA and CA19-9 had a reduction from baseline, with similar and substantial (median 83% - 96%) reductions across both markers in patients with objective responses and those with stable disease.

The enrollment in the randomized portion of the BEACON CRC trial is ongoing. Patients interested in participating in this trial may talk to their doctor to have their tumor tested for the BRAF mutation for eligibility to enroll in this new and important trial. Further details on the trial are available at clinicaltrials.gov (NCT02928224).

A PDF of the ASCO 2018 Gastrointestinal Cancers Symposium presentation can be found on Array's website: http://www.arraybiopharma.com/download_file/282/

*Overall response rate (ORR) = Complete response (CR) + Partial response (PR)

About BEACON CRC
BEACON CRC is a randomized, open-label, global trial evaluating the efficacy and safety of encorafenib, binimetinib and cetuximab in patients with *BRAF*-mutant metastatic CRC whose disease has progressed after one or two prior regimens. Thirty patients were treated in the safety lead-in and received the triplet combination (encorafenib 300 mg daily, binimetinib 45 mg twice daily and cetuximab per label). Of the 30 patients, 29 had a $BRAF^{V600E}$ mutation. Microsatellite instability-high (MSI-H), resulting from defective DNA mismatch repair, was detected in only 1 patient. As previously announced, the triplet combination demonstrated good tolerability, supporting initiation of the randomized portion of the trial.

The randomized portion of the BEACON CRC trial is designed to assess the efficacy of encorafenib in combination with cetuximab with or without binimetinib compared to cetuximab and irinotecan-based therapy. Approximately 615 patients are expected to be randomized 1:1:1 to receive triplet combination, doublet combination (encorafenib and cetuximab) or the control arm (irinotecan-based therapy and cetuximab). The primary endpoint of the trial is overall survival of the triplet combination compared to the control arm. Secondary endpoints address efficacy of the doublet combination compared to the control arm, and the triplet combination compared to the doublet therapy. Other secondary endpoints include PFS, ORR, duration of response, safety and tolerability. Health related quality of life data will also be assessed. The trial will be conducted at over 250 investigational sites in North America, South America, Europe and the Asia Pacific region. Patient enrollment is expected to be completed in 2018.

BEACON CRC is the first and only Phase 3 trial designed to test a BRAF/MEK combo targeted therapy in *BRAF*-mutant advanced CRC. Phase 2 trial results were presented at the 2016 ASCO annual meeting. [1] In the doublet arm of encorafenib and cetuximab, median overall survival (mOS) exceeded one year, which is more than double several separate historical published standard of care benchmarks for this population. [1-7] Further, the ORR was 22% and the mPFS was 4.2 months. [1] Historical published ORR and mPFS benchmarks in this patient population using standard of care regimens range between 4% to 8% and 1.8 and 2.5 months, respectively. [5-8]

About Colorectal Cancer
Worldwide, colorectal cancer is the third most common type of cancer in men and the second most common in women, with approximately 1.4 million new diagnoses in 2012. Of these, nearly 750,000 were diagnosed in men, and 614,000 in women. Globally in 2012, approximately 694,000 deaths were attributed to colorectal cancer. In the U.S. alone, an estimated 140,250 patients will be diagnosed with cancer of the colon or rectum in 2018, and

approximately 50,000 are estimated to die of their disease. [9] In the U.S., *BRAF* mutations are estimated to occur in 10% to 15% of patients with colorectal cancer and represent a poor prognosis for these patients. [3, 4, 10, 11] Based on recent prospective historical data, the prevalence of MSI-H in tumors from patients with metastatic *BRAF*-mutant CRC ranged from 14% in a recent Phase 1b/2 trial (NCT01719380) (Array, data on file) to 18% in a recent Southwestern Oncology Group (SWOG) randomized phase 2 trial. [7]

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 binimetinib.

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).

About Pierre Fabre
With a portfolio representing a continuum of activities spanning from prescription drugs and consumer healthcare products to dermo-cosmetics, Pierre Fabre is the 2nd largest dermo-cosmetics laboratory in the world, the 2nd largest private French pharmaceutical group and the market leader in France for products sold over the counter in pharmacies. Its portfolio includes several global brands and franchises among which Eau Thermale Avène - the worldwide dermo-cosmetic market leader - Klorane, Ducray, René Furterer, A-Derma, Galénic, Elancyl, Naturactive, Pierre Fabre Health Care, Pierre Fabre Oral Care, Pierre Fabre Dermatologie and Pierre Fabre Oncologie.

In 2016, Pierre Fabre generated 2,282 million euros in revenues, of which 60% came from its international business and 59% from its dermo-cosmetics division. Pierre Fabre, which has always been headquartered in the South-West of France, counts more than 13,000 employees worldwide, owns subsidiaries and offices in 47 countries and enjoys distribution agreements in over 130 countries. In 2016, Pierre Fabre dedicated ca. 195 million euros to its R&D efforts, split between oncology, central nervous system, consumer healthcare, dermatology and dermo-cosmetics.

Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan.

The independent French certification group AFNOR audited Pierre Fabre for its corporate social responsibility policy at the "exemplary" level, according to the ISO 26000 standard for CSR.

To find out more about Pierre Fabre, please go to www.pierre-fabre.com

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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 future 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 U.S.; 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 20, 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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