



Array BioPharma Reports Financial Results For The Second Quarter of Fiscal 2018

February 6, 2018

- **Encorafenib and binimetinib combination achieved a median overall survival (mOS) of 33.6 months in patients with BRAF-mutant melanoma in Phase 3 COLUMBUS trial -**
- **FDA target action date under PDUFA is June 30, 2018 for encorafenib and binimetinib NDAs in BRAF-mutant melanoma**
- **Combination of encorafenib, binimetinib and cetuximab demonstrated an 8 month median progression-free survival (mPFS) with a 48% confirmed ORR, including 3 complete responses in patients with BRAF-mutant colorectal cancer (CRC) in updated safety lead-in results from Phase 3 BEACON CRC trial -**
- **Immuno-oncology strategy to develop binimetinib in combination with PD-1/PD-L1 checkpoint inhibitors strengthened through collaborations with Bristol-Myers Squibb, Merck and now Pfizer -**

BOULDER, Colo., Feb. 6, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) today reported results for its second quarter of fiscal 2018 and provided an update on the progress of its key clinical development programs.

COLUMBUS PHASE 3 TRIAL

Treatment with the combination of encorafenib 450 mg daily and binimetinib 45 mg twice daily (COMBO450) reduced the risk of death compared to treatment with vemurafenib 960 mg daily [hazard ratio (HR) of 0.61, (95% CI 0.47, 0.79, $p < 0.001$)] in patients with *BRAF*-mutant melanoma in the Phase 3 COLUMBUS trial.

- Phase 3 trial showed mOS of 33.6 months for patients treated with COMBO450, compared to 16.9 months for patients treated with vemurafenib as a monotherapy.
- As previously announced, the combination of encorafenib and binimetinib was generally well-tolerated. Grade 3/4 adverse events (AEs) that occurred in more than 5% of patients receiving the combination were increased gamma-glutamyltransferase (GGT) (9%), increased blood creatine phosphokinase (CK) (7%) and hypertension (6%). The incidence of selected any grade AEs of special interest, defined based on toxicities commonly associated with commercially available BRAF+MEK-inhibitor treatments for patients receiving the combination of encorafenib and binimetinib included: rash (23%), pyrexia (18%), retinal pigment epithelial detachment (13%) and photosensitivity (5%). Full safety results of COLUMBUS Part 1 were presented at the 2016 Society for Melanoma Research Annual Congress.

The FDA:

- Continues review of Array's New Drug Applications (NDAs) to support use of the encorafenib and binimetinib combination for the treatment of patients with *BRAF*-mutant advanced, unresectable or metastatic melanoma
- Set a target action date under Prescription Drug User Fee Act (PDUFA) of June 30, 2018 for both applications
- Informed Array that, based on its preliminary review of the applications, it has not identified any potential review issues, and that it is not currently planning to hold an advisory committee meeting to discuss these NDAs

The regulatory submissions were based on findings from the pivotal Phase 3 [COLUMBUS](#) trial.

"We believe the strength of the COLUMBUS data, with a remarkable median overall survival of 33.6 months and median progression-free survival of 14.9 months, highlights the potential of the encorafenib and binimetinib combination for patients with *BRAF*-mutant melanoma," said Ron Squarer, Chief Executive Officer. "These data, together with our impressive, recently presented results in *BRAF*-mutant colorectal cancer, and our strong cash balance, position us well to advance our innovative therapies for patients with cancer."

BEACON CRC PHASE 3 TRIAL

Updated results from the 30 patient safety lead-in of the Phase 3 BEACON CRC trial evaluating the triplet combination of encorafenib, binimetinib and cetuximab, an EGFR antagonist, in patients with *BRAF*-mutant CRC whose disease has progressed after one or two prior regimens were presented at the ASCO 2018 Gastrointestinal Cancers Symposium.

- The estimated mPFS at the time of analysis was 8 months in 29 patients with *BRAF*^{V600E}-mutant CRC.
- The confirmed overall response rate (ORR) was 48% with 3 complete responses in patients with *BRAF*^{V600E}-mutant CRC. Further, the ORR was 62% in the 16 patients who received only one prior line of therapy.
- These data represent improvements compared to several separate historical published standard of care benchmarks for this population which range between 4% to 8% ORR and 1.8 and 2.5 months mPFS.
- The triplet combination was generally well-tolerated. Two patients discontinued treatment due to 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, urinary tract infection, increased aspartate aminotransferase (AST) and increased blood CK.
- Enrollment in the randomized portion of BEACON CRC is ongoing. *BRAF* mutations are estimated to occur in 10% to 15% of patients with CRC and represent a poor prognosis for these patients.

"Media progression-free survival of 8 months in the BEACON CRC safety lead-in represents an exciting result relative to historical benchmarks and is an encouraging signal for the success of the randomized portion of this trial," said Victor Sandor, M.D., Chief Medical Officer.

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

IMMUNO-ONCOLOGY COLLABORATIONS: TRIAL ADVANCING WITH BRISTOL-MYERS SQUIBB, TRIAL INITIATED WITH MERCK AND NEW COLLABORATION ANNOUNCED WITH PFIZER

Array is developing binimetinib in combination with PD-1 / PD-L1 checkpoint inhibitors. We have announced separate, strategic collaborations with Bristol-Myers Squibb, Merck and Pfizer, but in each case, are pursuing a unique trial design to explore different clinical approaches.

Bristol-Myers Squibb

- The clinical trial with Bristol-Myers Squibb continues to advance and is designed to investigate the safety, tolerability and efficacy of binimetinib in combination with nivolumab (anti-PD-1 therapy), with and without ipilimumab (CTLA-4 antibody), in patients with advanced metastatic microsatellite stable (MSS) CRC and the presence of a *RAS* mutation who have received one or two prior regimens.
- The trial is jointly supported by Array and Bristol-Myers Squibb and sponsored by Array.

Merck

- The clinical trial with Merck is designed to investigate the safety, tolerability and efficacy of binimetinib in combination with pembrolizumab (anti-PD-1 therapy), with and without FOLFOX or FOLFIRI (chemotherapy) in patients with CRC whose tumors are not microsatellite instability-high (MSI-H).
- After establishing combinability in separate Phase 1 cohorts, the trial will enroll expansion cohorts of 1st and 2nd-line CRC patients onto these novel triplet combinations to determine effectiveness.
- The trial will be sponsored and funded by Merck, with Array providing binimetinib supply.

Pfizer

- The clinical trial with Pfizer is designed to investigate the safety, tolerability and efficacy of several novel anti-cancer combinations, including binimetinib, avelumab (anti-PD-L1 therapy) and talazoparib (PARP inhibitor) across various tumor types.
- The multi-arm Phase 1b clinical trial is designed to establish recommended doses of different regimens combining the drugs.
- Initially, the focus will be in non-small cell lung cancer (NSCLC) and pancreatic cancer, with additional indications being explored at a later stage.
- The study is expected to begin by the third quarter of 2018, and results will be used to determine optimal approaches to further clinical development of these combinations.
- The trial will be sponsored and funded by Pfizer, with Array providing binimetinib supply.

NEW SUBSIDIARY FORMED TO ADVANCE ARRY-797

Array formed a wholly-owned subsidiary, Yarra Therapeutics, LLC, to further develop and commercialize therapeutics targeted towards rare diseases, including ARRY-797, an oral, selective p38 mitogen-activated protein kinase inhibitor. A Phase 3 trial of ARRY-797 in patients with LMNA A/C-related dilated cardiomyopathy is planned to begin this quarter. LMNA A/C-related dilated cardiomyopathy is a rare, degenerative cardiovascular disease caused by mutations in the LMNA gene and characterized by a poor prognosis.

FINANCIAL HIGHLIGHTS

Novartis Financial Commitment

Novartis continues to substantially fund all ongoing trials with encorafenib and binimetinib that were active or planned as of the close of the Novartis Agreements in 2015, including the COLUMBUS Phase 3 trial. Reimbursement revenue from Novartis was approximately \$88.5 million for the 12 months ended December 31, 2017, of which \$22.4 million was recorded in the quarter ended December 31, 2017. Total revenue and upfront payment collected from Novartis since the start of the 2015 agreement is \$348.7 million.

Second Quarter of Fiscal 2018 Compared to First Quarter of Fiscal 2018 (Sequential Quarters Comparison)

- **Revenue** for the second quarter of fiscal 2018 was \$42.2 million, compared to \$29.7 million for the prior quarter. The increase was primarily due to recognition of the remaining \$7.9 million deferral of the Asahi Kasei Pharma upfront payment resulting from completion of all remaining material obligations under the Collaboration and License Agreement, as well as higher Novartis reimbursement revenue.
- **Cost of partnered programs** for the second quarter of fiscal 2018 was \$13.7 million, compared to \$11.8 million for the prior quarter. The increase was primarily due to higher costs incurred for the BEACON CRC trial as it continues to advance, as well as additional resources engaged on collaborations.
- **Research and development expense** was \$42.6 million, compared to \$41.4 million in the prior quarter. The increase was driven by costs related to the increased activity on Novartis transitioned studies, and is partially offset by the non-recurring expense related to commercial and clinical supply from the previous quarter.
- **Loss from Operations** for the quarter was \$25.7 million, compared to a loss from operations of \$35.5 million in the previous quarter. The decrease in net loss was primarily due to increased revenue, which was partially offset by increased

research and development.

- **Net loss** for the second quarter was \$34.1 million, or (\$0.17) per share, compared to \$38.0 million, or (\$0.22) per share, in the prior quarter.
- **Cash, Cash Equivalents and Marketable Securities** as of December 31, 2017 were \$420 million.

Second Quarter of Fiscal 2018 Compared to Second Quarter of Fiscal 2017 (Prior Year Comparison)

- **Revenue** for the second quarter of fiscal 2018 decreased \$2.3 million compared to the same quarter of fiscal 2017. The decrease was primarily due to decreased reimbursement revenue for the Novartis transitioned studies, which was partially offset by revenue from new and expanded collaborations.
- **Cost of partnered programs** increased \$4.7 million compared to the second quarter of fiscal 2017. The increase was primarily due to higher costs incurred for the BEACON CRC trial, as well as more resources engaged on collaborations.
- **Research and development expense** decreased \$3.9 million, compared to the second quarter of fiscal 2017. The decrease was due to expenses associated with the Novartis transitioned studies.
- **Net loss** for the second quarter of fiscal 2018 was \$34.1 million, or (\$0.17) per share, compared to \$23.3 million, or (\$0.14) per share, for the same quarter in fiscal 2017. The increase in net loss was primarily due to a decrease in reimbursement revenue from Novartis and one-time costs to convert and extinguish Array's convertible debt.

CONFERENCE CALL INFORMATION

Array will hold a conference call on Tuesday, February 6, 2018 at 9:00 a.m. Eastern Time to discuss these results and provide an update on the progress of its key clinical development programs. Ron Squarer, Chief Executive Officer, will lead the call.

Date: Tuesday, February 6, 2018
Time: 9:00 a.m. Eastern Time
Toll-Free: (844) 464-3927
Toll: (765) 507-2598
Pass Code: 6187887

Webcast, including Replay and Conference Call Slides:

<https://edge.media-server.com/m6/p/qwxnqcb>

About COLUMBUS

The COLUMBUS trial, (NCT01909453), is a two-part, international, randomized, open label Phase 3 trial evaluating the efficacy and safety of the combination of encorafenib and binimetinib compared to vemurafenib and encorafenib monotherapy in 921 patients with locally advanced, unresectable or metastatic melanoma with *BRAF*^{V600} mutation. Prior immunotherapy treatment was allowed. Over 200 sites across North America, Europe, South America, Africa, Asia and Australia participated in the trial. Patients were randomized into two parts:

- In Part 1, 577 patients were randomized 1:1:1 to receive COMBO450, ENCO300, or vemurafenib 960 mg alone. The dose of encorafenib in the combination arm is 50% higher than the single agent maximum tolerated dose of 300 mg. A higher dose of encorafenib was possible due to improved tolerability when combined with binimetinib. The primary endpoint for the COLUMBUS trial was an mPFS comparison of the COMBO450 arm versus vemurafenib. mPFS is determined based on tumor assessment (RECIST version 1.1 criteria) by a Blinded Independent Central Review (BICR). Secondary endpoints include a comparison of the mPFS of ENCO300 to that of the COMBO450 arm and a comparison of OS for the COMBO450 arm to that of vemurafenib alone. Results from Part 1 of the COLUMBUS trial previously presented at the 2016 Society for Melanoma Research Annual Congress, showed that COMBO450 more than doubled mPFS) in patients with advanced *BRAF*-mutant melanoma, with a mPFS of 14.9 months compared with 7.3 months observed with vemurafenib [HR 0.54, (95% CI 0.41-0.71, p<0.001)]. In the secondary mPFS comparison of COMBO450 to ENCO300, ENCO300 demonstrated a mPFS of 9.6 months [HR 0.75, (95% CI 0.56-1.00, p=0.051)].
- In Part 2, 344 patients were randomized 3:1 to receive encorafenib 300 mg plus binimetinib 45 mg (COMBO300) or ENCO300. Part 2 was designed to provide additional data to help evaluate the contribution of binimetinib to the combination of encorafenib and binimetinib.

As the secondary endpoint comparison of mPFS between the COMBO450 arm and ENCO300 arm in Part 1 did not achieve statistical significance, the planned analysis of mOS is descriptive.

About Melanoma

Metastatic melanoma is the most serious and life-threatening type of skin cancer and is associated with low survival rates. [1, 2] There are about 200,000 new cases of melanoma diagnosed worldwide each year, approximately half of which have *BRAF* mutations, a key target in the treatment of metastatic melanoma. [1, 3, 4]

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 of 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 mOS 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. [5] In the doublet arm of encorafenib and cetuximab, mOS exceeded one year, which is more than double several separate historical published standard of care benchmarks for this population. [5-11] Further, the ORR was 22% and the mPFS was 4.2 months. [5] 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. [9-12]

About Colorectal Cancer

Worldwide, CRC 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. [13] Of these, nearly 750,000 were diagnosed in men, and 614,000 in women. [14] Globally in 2012, approximately 694,000 deaths were attributed to CRC. [13] 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. [13] In the U.S., BRAF mutations are estimated to occur in 10% to 15% of patients with CRC and represent a poor prognosis for these patients. [7, 8, 16, 17] 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. [11]

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: binimetinib (MEK162), encorafenib (LGX818), selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Cascadian Therapeutics). For more information on Array, please go to www.arraybiopharma.com.

References

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- [13] Global Cancer Facts & Figures 3rd Edition. American Cancer Society. Available at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/global-cancer-facts-and-figures/global-cancer-facts-and-figures-3rd-edition.pdf>. Accessed January 2018.
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- [16] Sorbye H, et al. *PLoS One.* 2015
- [17] Vecchione, et al. *Cell.* 2016

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 or approvals, 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 commercial-stage biopharmaceutical 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 February 6, 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.

Array BioPharma Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2017	2016	2017	2016
Revenue				
Reimbursement revenue	\$ 22,395	\$ 27,948	\$ 40,587	\$ 59,269
Collaboration and other revenue	8,508	6,030	16,516	12,319
License and milestone revenue	11,315	10,545	14,861	12,206
Total revenue	<u>42,218</u>	<u>44,523</u>	<u>71,964</u>	<u>83,794</u>
Operating expenses				
Cost of partnered programs	13,716	9,026	25,475	17,871
Research and development for proprietary programs	42,613	46,469	84,058	93,032
General and administrative	11,607	8,834	23,655	16,696
Total operating expenses	<u>67,936</u>	<u>64,329</u>	<u>133,188</u>	<u>127,599</u>
Loss from operations	(25,718)	(19,806)	(61,224)	(43,805)
Other income (expense)				
Loss on extinguishment and conversion of Notes	(6,457)	—	(6,457)	—
Impairment loss related to cost method investment	—	—	—	(1,500)
Change in fair value of notes payable	(300)	(600)	(100)	(800)
Interest income	1,255	212	1,780	282
Interest expense	(2,833)	(3,107)	(6,046)	(6,086)
Total other expense, net	<u>(8,335)</u>	<u>(3,495)</u>	<u>(10,823)</u>	<u>(8,104)</u>
Net loss	<u>\$ (34,053)</u>	<u>\$ (23,301)</u>	<u>\$ (72,047)</u>	<u>\$ (51,909)</u>
Net loss per share – basic	<u>\$ (0.17)</u>	<u>\$ (0.14)</u>	<u>\$ (0.38)</u>	<u>\$ (0.33)</u>
Net loss per share – diluted	<u>\$ (0.17)</u>	<u>\$ (0.14)</u>	<u>\$ (0.38)</u>	<u>\$ (0.33)</u>
Weighted average shares outstanding – basic	<u>199,852</u>	<u>168,127</u>	<u>187,312</u>	<u>156,613</u>
Weighted average shares outstanding – diluted	<u>199,852</u>	<u>168,127</u>	<u>187,312</u>	<u>156,613</u>

Summary Balance Sheet Data
(Unaudited)
(in thousands)

	December 31, 2017	June 30, 2017
Cash, cash equivalents and marketable securities	\$ 420,317	\$ 235,055
Working capital	\$ 380,243	\$ 200,626
Total assets	\$ 462,845	\$ 279,145
Long-term debt, net	\$ 93,264	\$ 121,305
Total stockholders' equity	\$ 242,182	\$ 11,727

CONTACT:

Array BioPharma

Andrea N. Flynn, Ph.D.

Senior Director, Investor Relations & Corporate Communications

(303) 381-6600

ir@arraybiopharma.com



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