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

May 9, 2018

-- June 30, 2018 PDUFA date for encorafenib and binimetinib NDAs in BRAF-mutant melanoma --

-- 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 --

-- Combination of encorafenib, binimetinib and cetuximab demonstrated an 8 month median progression-free survival (mPFS) in patients with BRAF-mutant colorectal cancer (CRC) in updated safety lead-in results from Phase 3 BEACON CRC trial --

-- Cash, Cash Equivalents and Marketable Securities as of March 31, 2018 were $440 million --

BOULDER, Colo., May 9, 2018 /PRNewswire/ -- Array BioPharma Inc., (Nasdaq: ARRY) today reported results for its third quarter of fiscal 2018 and provided an update on the progress of its key clinical development programs.

"Preparations for the anticipated U.S. launch of encorafenib and binimetinib in *BRAF*-mutant melanoma are well underway," said Ron Squarer, Chief Executive Officer. "We are pleased to have our entire commercial leadership and infrastructure in place and are poised for an exciting 2018, as we look ahead to commercialization and additional data updates from our encorafenib and binimetinib clinical trials."

COLUMBUS PHASE 3 TRIAL

Regulatory

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 remain under review by the FDA with a target action date under Prescription Drug User Fee Act (PDUFA) of June 30, 2018.

The European Medicines Agency (EMA), as well as the Swiss Medicines Agency (Swissmedic) and the Australian Therapeutic Goods Administration (TGA), are reviewing the Marketing Authorization Applications (MAAs) submitted by Pierre Fabre and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has accepted the Manufacturing and Marketing Approval (MMA) applications submitted by Ono Pharmaceutical Co, Ltd.

The regulatory submissions were based on findings from the pivotal Phase 3 COLUMBUS trial.

COLUMBUS Median Overall Survival Results

Array will announce additional results from the Phase 3 COLUMBUS trial in an oral presentation (Abstract #223875) at the American Society of Clinical Oncology 2018 Annual Meeting on June 4.

Array previously announced that 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.

- The 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 reported, 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 (22%), pyrexia (18%), serous retinopathy including retinal pigment epithelial detachment (20%) and photosensitivity (5%). Full safety results of COLUMBUS Part 1 were published in *The Lancet Oncology*.

The Lancet Oncology Publication

Detailed results of the pivotal Phase 3 COLUMBUS trial for the treatment of patients with *BRAF*-mutant advanced, unresectable or metastatic melanoma were published online on March 21, 2018 and in the May 2018 print edition of *The Lancet Oncology*.

BEACON CRC PHASE 3 TRIAL

Array will present updated results from the 30 patient safety lead-in of the Phase 3 BEACON CRC trial at the ESMO 20thWorld Congress on Gastrointestinal CancerJune 20-23, 2018.

Array previously announced 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 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 approved standard of care benchmarks for this population which range between 4% to 8% ORR and 1.8 and 2.5 months mPFS. [1-4]

- 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.

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

IMMUNO-ONCOLOGY COLLABORATIONS: TRIALS ADVANCING WITH BRISTOL-MYERS SQUIBB AND MERCK; TRIAL WITH PFIZER EXPECTED TO START THIRD QUARTER OF 2018

Array is developing binimetinib in combination with PD-1/ PD-L1 checkpoint inhibitors and has 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 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 continues to advance and 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).
- The trial is sponsored and funded by Merck, with Array providing binimetinib supply.

Pfizer

- The clinical trial 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 and is expected to begin during the third quarter of 2018.
- 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 trial will be sponsored and funded by Pfizer, with Array providing binimetinib supply.

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 $87 million for the 12 months ended March 31, 2018, of which $24.8 million was recorded in the quarter ended March 31, 2018. Total revenue and upfront payment collected from Novartis since the start of the 2015 agreement is $373.5 million.

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

- **Revenue** for the third quarter of fiscal 2018 was $66.4 million, compared to $42.2 million for the prior quarter. The increase was primarily due to an upfront license fee from ASLAN Pharmaceuticals as well as higher Novartis reimbursement revenue.
- **Cost of partnered programs** for the third quarter of fiscal 2018 was $17.7 million, compared to $13.7 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 for proprietary programs** was $53.6 million, compared to $42.6 million in the prior quarter. The increase was driven by higher activity on the Novartis transitioned studies and pre-commercial manufacturing costs for encorafenib and binimetinib.
- **Loss from Operations** for the quarter was $21.8 million, compared to a loss from operations of $25.7 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 expense.
- **Net loss** for the second quarter was $22.9 million, or ($0.11) per share, compared to $34.1 million, or ($0.17) per share, in the prior quarter.
- **Cash, Cash Equivalents and Marketable Securities** as of March 31, 2018 were $440 million.

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

- **Revenue** for the third quarter of fiscal 2018 increased by $33.1 million compared to the same quarter of fiscal 2017. The increase was primarily due to the ASLAN Pharmaceuticals upfront license fee.

- **Cost of partnered programs** increased $10.3 million compared to the third 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 for proprietary programs** increased $7.6 million, compared to the third quarter of fiscal 2017. The increase was driven by higher activity on the Novartis transitioned studies and pre-commercial manufacturing costs for encorafenib and binimetinib.
- **Net loss** for the third quarter of fiscal 2018 was $22.9 million, or ($0.11) per share, compared to $35.3 million, or ($0.21) per share, for the same quarter in fiscal 2017. The decrease in net loss was primarily due to increased revenue, which was partially offset by increased research and development expense.

CONFERENCE CALL INFORMATION
Array will hold a conference call on Wednesday, May 9, 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: Wednesday, May 9, 2018
Time: 9:00 a.m. Eastern Time
Toll-Free: (844) 464-3927
Toll: (765) 507-2598
Pass Code: 6465079

Webcast, including Replay and Conference Call Slides:
https://edge.media-server.com/m6/p/s5fgkv2a

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, encorafenib, 300 mg daily (ENCO 300), or vemurafenib, 960 mg twice daily 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 COMBO450 arm to that of ENCO300 and a comparison of overall survival (OS) in patients treated in 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<0.0001)]. 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 twice daily (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 protocol specified analysis of OS is descriptive.

About Melanoma
Metastatic melanoma is the most serious and life-threatening type of skin cancer and is associated with low survival rates. [5, 6] 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. [5, 7, 8]

About BEACON CRC
BEACON CRC is the first and only Phase 3 trial designed to test a BRAF/MEK combo targeted therapy in *BRAF*-mutant advanced 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.

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. [9] Of these, nearly 750,000 were diagnosed in men, and 614,000 in women. [10] Globally in 2012, approximately 694,000 deaths were attributed to CRC. [9] 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. [11] 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. [12, 13, 14, 15] 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. [3]

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 and other conditions. Ten registration studies are currently advancing related to eight Array-owned or partnered drugs: encorafenib (LGX818), binimetinib (MEK162), ARRY-797, selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Seattle Genetics). For more information on Array, please go to www.arraybiopharma.com.

References

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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 May 9, 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 March 31,		Nine Months Ended March 31,	
	2018	**2017**	**2018**	**2017**
Revenue				

Reimbursement revenue	$ 24,751	$ 26,085	$ 65,338	$ 85,354
Collaboration and other revenue	10,113	5,530	26,629	17,849
License and milestone revenue	31,503	1,665	46,364	13,871
Total revenue	66,367	33,280	138,331	117,074
Operating expenses				
Cost of partnered programs	17,712	7,432	43,187	25,303
Research and development for proprietary programs	53,636	46,069	137,694	139,101
Selling, general and administrative	16,773	11,714	40,428	28,410
Total operating expenses	88,121	65,215	221,309	192,814
Loss from operations	(21,754)	(31,935)	(82,978)	(75,740)
Other income (expense)				
Loss on extinguishment and conversion of Notes	—	—	(6,457)	—
Impairment loss related to cost method investment	—	—	—	(1,500)
Realized gains on investments and other	69	785	69	785
Change in fair value of notes payable	(100)	(1,300)	(200)	(2,100)
Interest income	1,295	228	3,075	510
Interest expense	(2,361)	(3,095)	(8,407)	(9,181)
Total other expense, net	(1,097)	(3,382)	(11,920)	(11,486)
Net loss	$ (22,851)	$ (35,317)	$ (94,898)	$ (87,226)
Net loss per share – basic	$ (0.11)	$ (0.21)	$ (0.49)	$ (0.54)
Net loss per share – diluted	$ (0.11)	$ (0.21)	$ (0.49)	$ (0.54)
Weighted average shares outstanding – basic	208,994	169,020	194,434	160,689
Weighted average shares outstanding – diluted	208,994	169,020	194,434	160,689

Summary Balance Sheet Data
(Unadudited)
(in thousands)

	March 31, 2018	June 30, 2017
Cash, cash equivalents and marketable securities	$ 439,518	$ 235,055
Working capital	$ 402,701	$ 200,626
Total assets	$ 497,007	$ 279,145
Long-term debt, net	$ 94,555	$ 121,305
Total stockholders' equity	$ 265,150	$ 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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