Array BioPharma Reports Financial Results For The Third Quarter Of Fiscal 2017

May 10, 2017

BOULDER, Colo., May 10, 2017 /PRNewswire/ --

- COLUMBUS / BRAF-mutant melanoma Part 2 demonstrates positive results and New Drug Application (NDA) filing on track for June or July 2017
- New Binimetinib / KEYTRUDA® collaboration initiated with Merck
- BEACON CRC Phase 3 enrollment underway based on an attractive safety profile and with early encouraging activity from safety lead-in
- Cash, Cash Equivalents and Marketable Securities as of March 31, 2017 were $207 million

Array BioPharma Inc. (Nasdaq: ARRY), a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule cancer therapies, today reported results for its third quarter of fiscal 2017 and provided an update on the progress of its key clinical development programs.

COLUMBUS PHASE 3 TRIAL: Positive Part 2 Results Announced
On May 9, 2017, Array announced top-line results from Part 2 of the Phase 3 COLUMBUS study evaluating binimetinib, a MEK inhibitor, and encorafenib, a BRAF inhibitor, in patients with *BRAF*-mutant advanced, unresectable or metastatic melanoma. The primary analysis of Part 2 compared progression free survival (PFS) in patients treated with binimetinib 45mg twice daily plus encorafenib 300mg daily (COMBO300) to patients treated with encorafenib 300mg daily as a single agent. The median PFS (mPFS) for patients treated with COMBO300 was 12.9 months compared to 9.2 months for patients treated with single agent encorafenib, with a HR of 0.77 [95% CI 0.61-0.97, p=0.029]. COMBO300 was generally well-tolerated and reported dose intensity and adverse events were consistent with binimetinib (45mg twice daily) plus encorafenib 450mg daily (COMBO450) results from Part 1 of the COLUMBUS trial. Part 2 of COLUMBUS was designed specifically to assess the contribution of binimetinib to the combination of binimetinib and encorafenib by reducing the dose of encorafenib to 300mg in the combination arm to allow for a comparison of equal doses across arms. Further results from Part 2 will be presented at a medical meeting during the second half of 2017.

"The robust PFS benefit and tolerability observed with binimetinib plus encorafenib in COLUMBUS suggest the combination represents a potential important addition to the MEK/BRAF treatment landscape for patients with *BRAF*-mutant melanoma," said Ron Squarer, Chief Executive Officer, Array BioPharma.

Based on the strength of data from Part 1 and Part 2, Array is on track to file an NDA for COLUMBUS in June or July 2017. The primary endpoint for the COLUMBUS trial is a PFS comparison of COMBO450 versus vemurafenib in Part 1. Array's European partner, Pierre Fabre, remains on track to file the Marketing Authorization Application during the summer.

Melanoma is the fifth most common cancer among men and the sixth most common cancer among women in the United States, with more than 87,000 new cases and over 9,700 deaths from the disease expected in 2017. Novel therapies that target the RAS-RAF-MEK-ERK pathway have a strong scientific rationale for activity in this disease, as up to 50 percent of patients with metastatic melanoma have activating BRAF mutations, the most common gene mutation in this patient population. Currently marketed MEK/BRAF combination agents have a run rate approaching $1 billion in annual worldwide sales.

MERCK COLLABORATION: Binimetinib and KEYTRUDA combination trial announced in MSS colorectal cancer patients
Array entered into a clinical trial collaboration agreement with Merck to investigate the safety and efficacy of binimetinib with Merck's anti-PD-1 therapy, KEYTRUDA (pembrolizumab), in metastatic colorectal cancer patients with microsatellite stable tumors (MSS CRC). The companies entered into this collaboration based on the growing body of preclinical and clinical evidence that the immune activity of an anti-PD-1 therapy, such as KEYTRUDA, can be enhanced when combined with a MEK inhibitor, such as binimetinib.

Under the agreement, Array and Merck will collaborate on a clinical trial to investigate the safety and efficacy of the combination of binimetinib with KEYTRUDA, in MSS CRC patients. The trial is expected to establish a recommended dose regimen of binimetinib and KEYTRUDA, as well as explore the preliminary anti-tumor activity of several novel regimens. The study is expected to begin in the second half of 2017. Results from this first study will be used to determine optimal approaches to further clinical development of these combinations.

Merck will act as the sponsor of this clinical trial, and Array will supply Merck with binimetinib for use in the trial. This agreement does not include a non-competition provision that generally prohibits Merck or Array from entering into agreements with third parties to perform other clinical studies.

BEACON CRC PHASE 3 TRIAL: Randomized portion of trial now enrolling; patients receiving treatment
Array is advancing BEACON CRC, a global Phase 3 trial of encorafenib and Erbitux® (cetuximab), with or without binimetinib, versus standard of care in patients with BRAF-mutant CRC who have previously received first- or second-line systemic therapy. Based on an attractive safety profile and with early encouraging clinical activity observed in the safety lead-in, the randomized portion of the trial is now enrolling and patients are receiving treatment. Array expects to present early data from the safety lead-in later this year.

BEACON CRC was initiated based on results from a Phase 2 study including the combination of encorafenib and cetuximab in patients with advanced

BRAF-mutant CRC, which were presented at the 2016 ASCO annual meeting. In this study median Overall Survival for these patients exceeded one year, which is more than double several historical published benchmarks for this population.

Colorectal cancer is the second most common cancer among men and third most common cancer among women in the United States, with more than 135,000 new cases and more than 50,000 deaths from the disease projected in 2017. In the United States, BRAF mutations occur in 8 to 15 percent of patients with colorectal cancer and represent a poor prognosis for these patients.

ARRY-382 + KEYTRUDA PHASE 1/2 TRIAL: Phase 1b/2 expansions to begin shortly
Array is advancing a Phase 1/2 dose escalation immuno-oncology trial of ARRY-382 in combination with KEYTRUDA, in patients with advanced solid tumors. ARRY-382 is a wholly-owned, highly selective and potent, small molecule inhibitor of CSF-1R kinase activity. Planned expansions include patients with melanoma and non-small cell lung cancer.

FINANCIAL HIGHLIGHTS
Novartis continues to substantially fund all ongoing trials with binimetinib and encorafenib that were active or planned as of the close of the Novartis Agreements in 2015, including the NEMO and COLUMBUS Phase 3 trials. Reimbursement revenue from Novartis was approximately $119 million for the previous 12 months, of which $26 million was recorded over the quarter ending March 31, 2017.

Third Quarter of Fiscal 2017 Compared to Second Quarter of Fiscal 2017 (Sequential Quarters Comparison)

- **Revenue** for the third quarter of fiscal 2017 was $33.3 million, compared to $44.5 million for the prior sequential quarter. The decrease was primarily due to non-recurring milestones received in the prior quarter.
- **Cost of partnered programs** for the third quarter of fiscal 2017 was $7.4 million, compared to $9.0 million for the prior quarter.
- **Research and development expense** was $46.1 million, compared to $46.5 million in the prior quarter.
- **Loss from Operations** for the quarter was $31.9 million, which includes $2.9 million of stock-based compensation and $0.5 million of depreciation expense. This compares to a loss from operations of $20.0 million in the previous quarter, which included $2.1 million of stock-based compensation and $0.5 million of depreciation expense.
- **Net loss** for the third quarter was $35.3 million, or ($0.21) per share, compared to $23.3 million, or ($0.14) per share, in the prior quarter. The increase in net loss was primarily due to non-recurring milestones received in the prior quarter.
- **Cash, Cash Equivalents and Marketable Securities** as of March 31, 2017 were $207 million.

Third Quarter of Fiscal 2017 Compared to Third Quarter of Fiscal 2016 (Prior Year Comparison)

- **Revenue** for the third quarter of fiscal 2017 decreased $9.8 million compared to the same quarter of fiscal 2016. The decrease was primarily due to decreased reimbursement revenue for the Novartis transitioned studies.
- **Cost of partnered programs** increased $1.6 million compared to the third quarter of fiscal 2016. The increase was primarily due to higher costs incurred for the BEACON CRC trial.
- **Research and development expense** decreased $2.7 million, compared to the third quarter of fiscal 2016. The decrease was due to greater expenses associated with the Novartis transitioned binimetinib and encorafenib studies.
- **Net loss** for the third quarter of fiscal 2017 was $35.3 million, or ($0.21) per share, compared to $22.7 million, or ($0.16) per share, for the same quarter in fiscal 2016.

LEADERSHIP
Array announced that Shalini Sharp, Chief Financial Officer and Executive Vice President of Ultragenyx Pharmaceutical Inc., joined the company's Board of Directors, effective April 27, 2017. Ms. Sharp has been appointed to the Audit Committee of the Board.

CONFERENCE CALL INFORMATION
Array will hold a conference call on Wednesday, May 10, 2017 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 10, 2017
Time:	9:00 a.m. Eastern Time
Toll-Free:	(844) 464-3927
Toll:	(765) 507-2598
Pass Code:	92608803

Webcast, including Replay and Conference Call Slides: http://edge.media-server.com/m/p/hgm92o9w

About the Phase 3 COLUMBUS Study
The COLUMBUS trial, (NCT01909453), is a two-part, international, randomized, open label Phase 3 study evaluating the efficacy and safety of the combination of binimetinib plus encorafenib 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 study. Patients were randomized into two parts:

- In COLUMBUS Part 1, 577 patients were randomized 1:1:1 to receive 45mg binimetinib plus 450mg encorafenib (COMBO450), 300mg encorafenib alone, or 960mg vemurafenib alone. The dose of encorafenib in the combination arm is 50% higher than the single agent maximum tolerated dose of 300mg. A higher dose of encorafenib was possible due to improved tolerability when combined with binimetinib. The primary endpoint for the COLUMBUS trial was a PFS comparison of COMBO450 versus vemurafenib. PFS 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 PFS of encorafenib monotherapy to that of COMBO450 and a comparison of overall survival (OS) for COMBO450 to that of vemurafenib alone.

In November 2016, results from Part 1 were presented at the Society for Melanoma Research Annual Congress. The study met its primary endpoint, with COMBO450 significantly improving PFS compared with vemurafenib alone. In the analysis of the primary endpoint, the mPFS for patients treated with COMBO450 was 14.9 months versus 7.3 months for patients treated with vemurafenib; hazard ratio (HR) 0.54, (95% CI 0.41-0.71, P<0.001). As part of the trial design, the primary analysis was based on a BICR of patient scans, while results by local review at the investigative site were also analyzed. The chart below outlines the mPFS results, as determined by both assessments, for COMBO450 versus vemurafenib, COMBO450 versus encorafenib, and encorafenib versus vemurafenib:

	mPFS BICR		mPFS Local Review	
COMBO450 vs. Vemurafenib	**COMBO450**	**Vemurafenib**	**COMBO450**	**Vemurafenib**
	14.9 months	7.3 months	14.8 months	7.3 months
	HR (95% CI): 0.54 (0.41-0.71); P<0.001		HR (95% CI): 0.49 (0.37-0.64); P<0.001	
COMBO450 vs. Encorafenib	**COMBO450**	**Encorafenib**	**COMBO450**	**Encorafenib**
	14.9 months	9.6 months	14.8 months	9.2 months
	HR (95% CI): 0.75 (0.56-1.00); P=0.051		HR (95% CI): 0.68 (0.52-0.90); P=0.006	
Encorafenib vs. Vemurafenib	**Encorafenib**	**Vemurafenib**	**Encorafenib**	**Vemurafenib**
	9.6 months	7.3 months	9.2 months	7.3 months
	HR (95% CI): 0.68 (0.52-0.90); P=0.007		HR (95% CI): 0.70 (0.54-0.91); P=0.008	

COMBO450 was generally well-tolerated and reported adverse events (AEs) were overall consistent with previous bini/enco combination clinical trial results in BRAF-mutant melanoma patients. Grade 3/4 AEs which occurred in more than 5 percent of patients receiving COMBO450 included increased gamma-glutamyltransferase (GGT), increased blood creatine phosphokinase (CK), and hypertension. The incidence of AEs of special interest (toxicities commonly associated with commercially available MEK+BRAF-inhibitor treatments), for patients receiving COMBO450 included: rash (23 percent), pyrexia (18 percent), retinal pigment epithelial detachment (13 percent) and photosensitivity (5 percent).

- In COLUMBUS Part 2, 344 patients were randomized 3:1 to receive 45mg binimetinib plus 300mg encorafenib or 300mg encorafenib alone. Part 2 was designed to provide additional data to help evaluate the contribution of binimetinib to the combination of binimetinib and encorafenib. As the comparison of COMBO450 to encorafenib in Part 1 did not achieve statistical significance, the statistical analysis conducted in Part 2 is descriptive.

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 seven drugs: binimetinib (MEK162), encorafenib (LGX818), selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), larotrectinib (partnered with Loxo Oncology), tucatinib (partnered with Cascadian Therapeutics) and ipatasertib (partnered with Genentech).

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 for binimetinib/encorafenib, 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 May 10, 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.

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2017	2016	2017	2016
Revenue				
Reimbursement revenue - Novartis	$ 26,085	$ 36,941	$ 85,354	$ 73,912
Collaboration revenue	5,530	5,249	17,849	18,800
License and milestone revenue	1,665	857	13,871	1,962
Total revenue	33,280	43,047	117,074	94,674
Operating expenses				
Cost of partnered programs	7,432	5,847	25,303	17,722
Research and development for proprietary programs	46,069	48,802	139,101	111,151
General and administrative	11,714	8,406	28,410	25,702
Total operating expenses	65,215	63,055	192,814	154,575
Loss from operations	(31,935)	(20,008)	(75,740)	(59,901)
Other income (expense)				
Impairment loss related to cost method investment	-	-	(1,500)	-
Realized gain on investments and other	785	-	785	-
Change in fair value of notes payable	(1,300)	-	(2,100)	-
Interest income	228	76	510	167
Interest expense	(3,095)	(2,743)	(9,181)	(8,092)
Total other expense, net	(3,382)	(2,667)	(11,486)	(7,925)
Net loss	$ (35,317)	$ (22,675)	$ (87,226)	$ (67,826)
Net loss per share - basic	$ (0.21)	$ (0.16)	$ (0.54)	$ (0.47)
Net loss per share - diluted	$ (0.21)	$ (0.16)	$ (0.54)	$ (0.47)
Weighted average shares outstanding - basic	169,020	143,338	160,689	142,792
Weighted average shares outstanding - diluted	169,020	143,338	160,689	142,792

Summary Balance Sheet Data
(in thousands)

	March 31, 2017	June 30, 2016
Cash, cash equivalents and marketable securities	$ 207,392	$ 110,538
Working capital	$ 175,701	$ 102,867
Total assets	$ 256,202	$ 168,900
Long-term debt, net	$ 119,394	$ 113,655
Stockholders' equity	$ 27,714	$ (37,932)

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