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

February 9, 2017

- COLUMBUS / BRAF-mutant melanoma New Drug Application (NDA) expected to file in June or July -

- NEMO / NRAS-mutant melanoma target action date under the Prescription Drug User Fee Act (PDUFA) on June 30, 2017 -

- Binimetinib enhances PD-1 inhibitor anti-tumor activity in immunocompetent non-clinical models including colorectal cancer -

- Clinical results of selumetinib in pediatric patients with neurofibromatosis type 1 (NF1) and plexiform neurofibromas published in the New England Journal of Medicine; New trial announced for binimetinib in NF1 -

- Cash, Cash Equivalents and Marketable Securities as of December 31, 2016 were $214.8 million -

BOULDER, Colo., Feb. 9, 2017 /PRNewswire/ -- 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 second quarter of fiscal 2017 and provided an update on the progress of its key clinical development programs.

"We were pleased to report that COLUMBUS met its primary endpoint and demonstrated a robust PFS benefit associated with the combination of binimetinib plus encorafenib versus vemurafenib in patients with BRAF-mutant melanoma," said Ron Squarer, Chief Executive Officer of Array BioPharma. "Following a pre-NDA meeting with the FDA, we expect to file an NDA for COLUMBUS in June or July."

KEY COMPANY AND PIPELINE UPDATES

Binimetinib (MEK162) and encorafenib (LGX818)

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 $130 million for the previous 12 months, of which $27.9 million was recorded over the quarter ending December 31, 2016.

COLUMBUS: Global Phase 3 trial of binimetinib plus encorafenib versus vemurafenib in BRAF-mutant melanoma patients

In November 2016, results from the pivotal Phase 3 COLUMBUS trial of binimetinib plus encorafenib (bini/enco) treatment in *BRAF*-mutant melanoma patients were presented at the Society for Melanoma Research Annual Congress. The study met its primary endpoint, with the combination of bini/enco significantly improving progression free survival (PFS) compared with vemurafenib, a BRAF inhibitor, alone. In the analysis of the primary endpoint, the median PFS (mPFS) for patients treated with the combination of bini/enco 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 Blinded Independent Central Review (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 the combination of bini/enco versus vemurafenib, bini/enco versus encorafenib, and encorafenib versus vemurafenib:

	mPFS BICR		mPFS Local Review	
Bini/Enco vs. Vemurafenib	**Bini/Enco**	**Vemurafenib**	**Bini/Enco**	**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	
Bini/Enco vs. Encorafenib	**Bini/Enco**	**Encorafenib**	**Bini/Enco**	**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	

The combination of bini/enco also demonstrated an improvement in confirmed overall response rate (ORR; complete response plus partial response), the ability to deliver a high dose intensity to the majority of patients as well as an advantage in terms of maintaining quality of life for patients.

	Confirmed ORR BICR	Confirmed ORR Local Review
Bini/Enco	63% (95% CI: 56-70%)	75% (95% CI: 68-81%)
Vemurafenib	40% (95% CI: 33-48%)	49% (95% CI: 42-57%)
Encorafenib	51% (95% CI: 43-58%)	58% (95% CI: 50-65%)

- Median duration of exposure was approximately 51 weeks for patients receiving bini/enco, versus 31 weeks and 27 weeks for the encorafenib and vemurafenib monotherapy arms, respectively.

- Median dose intensity for patients treated with bini/enco was 100 percent (encorafenib) and 99.6 percent (binimetinib).
- 5 percent of bini/enco patients had received prior treatment with check-point inhibitors, including ipilimumab, anti-PD-1 and/or anti-PD-L1 therapies, and the observed clinical activity for these patients was generally consistent with that of bini/enco patients who had not received prior immunotherapy.
- The Quality of Life (QoL) measures were consistent between two scales and showed an advantage in terms of maintaining quality of life for patients receiving bini/enco compared to patients treated with either encorafenib or vemurafenib single agent therapy. The QoL scales used were the EORTC Quality of Life Questionnaire Core 30 and FACT-Melanoma Scale Score (Functional Assessment of Cancer Therapy).

The combination of bini/enco 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 bini/enco 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 bini/enco included: rash (23 percent), pyrexia (18 percent), retinal pigment epithelial detachment (13 percent) and photosensitivity (5 percent).

In addition, following discussions with the Independent Data Monitoring Committee (DMC), COLUMBUS clinical investigators were instructed in January 2017 to notify all study participants of the results of the trial and to offer only vemurafenib patients alternative treatments with approved MEK/BRAF inhibitors. Array expects to file an NDA for COLUMBUS in June or July, with data from both Part 1 and Part 2 of the study. We believe Pierre Fabre remains on track to file the MAA during 2017. Binimetinib and encorafenib are investigational medicines and are not currently approved in any country.

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. Current marketed MEK/BRAF combination agents have a run rate approaching $1 billion in annual worldwide sales.

NEMO: Global Phase 3 trial of binimetinib versus dacarbazine in NRAS-mutant melanoma patients
In September 2016, Array announced that the FDA accepted its NDA for binimetinib in NRAS-mutant melanoma, with a target action date under the Prescription Drug User Fee Act (PDUFA) of June 30, 2017. Also, the binimetinib Marketing Authorization Application (MAA) submitted by Pierre Fabre was validated and is currently under evaluation by the Committee for Medicinal Products for Human Use (CHMP). The FDA indicated that it plans to hold an advisory committee meeting (ODAC) in the first half of 2017 as part of the review process.

Activating NRAS mutations are present in approximately 20 percent of patients with metastatic melanoma, and are a poor prognostic indicator for these patients. Treatment options for this population remain limited beyond immunotherapy, and these patients face poor clinical outcomes and high mortality.

BEACON CRC: Global Phase 3 trial of binimetinib, encorafenib and Erbitux® (cetuximab) versus Erbitux in BRAF-mutant colorectal cancer (CRC) patients
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. The study includes a safety lead-in with approximately 30 patients. Enrollment in the safety lead-in continues following a planned DMC review of the initial cohort. Array expects to complete patient enrollment with the safety lead-in in March and initiate randomization of patients in April. Array continues to expect early data from the triplet lead-in later this year.

BEACON CRC was initiated based on results from a Phase 2 study of the combination of encorafenib and cetuximab, with or without alpelisib, a selective PI3K alpha inhibitor, in patients with advanced BRAF-mutant CRC, which were presented at the 2016 ASCO meeting. In this study mOS 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.

New NF1 Study: Phase 2 trial of binimetinib in patients with Neurofibromatosis Type 1 (NF1)
In collaboration with Neurofibromatosis Consortium, Array is participating in a Phase 2 study of binimetinib in children and adults with NF1 associated Plexiform Neurofibromas. The study will enroll approximately 40 NF1 patients to determine the objective response to binimetinib defined as a 20 percent or greater tumor volume reduction by MRI. In addition, duration of response, assessment of quality of life, pain, functional outcomes, and safety and tolerability will be assessed.

Results from a prior Phase 1 NF1 trial of selumetinib, a MEK inhibitor also invented at Array, were recently published in the *New England Journal of Medicine*, supporting further study of a MEK inhibitor in this patient population.

Non-clinical studies with MEK/PD-1
Binimetinib Enhances a Programmed Cell Death Receptor 1 (PD-1) Inhibitor Anti-Tumor Activity in Immunocompetent Preclinical Models
Array is evaluating MEK's contribution to immunotherapy in non-clinical cancer models, including models for CRC and pancreatic cancer.

In a CRC model, the combination of binimetinib with immunotherapy demonstrates enhanced tumor growth inhibition, providing support for the potential mechanistic synergies between immunotherapy and MEK inhibition.

In a pancreatic cancer model, the combination treatment group shows enhanced survival (i.e., PFS) with the addition of binimetinib to anti-PD-1 antibody treatment, compared to single agent anti-PD-1 treatment. Definitive tumor growth inhibition and survival studies in this model are ongoing.

Given the potential to improve clinical outcomes, as supported by these non-clinical studies, Array believes that MEK / anti-PD1 combinations are appropriate regimens to study in a number of cancer indications.

ARRY-382

Phase 1/2 dose escalation study advancing with ARRY-382, a colony-stimulating factor-1 receptor (CSF-1R) inhibitor, in combination with pembrolizumab, a PD-1 antibody, for the treatment of patients with advanced solid tumors

Array is advancing a Phase 1/2 dose escalation immuno-oncology trial of ARRY-382 in combination with pembrolizumab (Keytruda®), a PD-1 antibody, in patients with advanced solid tumors. ARRY-382 is a wholly-owned, highly selective and potent, small molecule inhibitor of CSF-1R kinase activity.

Enrollment in the Phase 1 portion of the trial continues following a planned DMC review of the initial dose level. Array expects to complete the Phase 1 portion of the trial in March and to initiate Phase 2 expansions in melanoma and non-small lung cancer during April.

ARRY-797 (ARRY-371797)

Phase 2 trial in patients with LMNA A/C-related dilated cardiomyopathy (LMNA-related DCM)

Based on data to date from a Phase 2 study of ARRY-797, an oral, selective p38 mitogen-activated protein kinase inhibitor, in patients with LMNA-related DCM a rare, degenerative cardiovascular disease caused by mutations in the LMNA gene and characterized by poor prognosis. Array plans to initiate a Phase 3 trial of ARRY-797 this summer as we evaluate options regarding the asset, including advancing it internally, partnering the program for further development and commercialization or creating a separate company.

SELUMETINIB

Phase 1 trial results in pediatric patients with neurofibromatosis type 1 (NF1) and plexiform neurofibromas published in the *New England Journal of Medicine*

In a Phase 1 clinical trial of selumetinib, a MEK inhibitor, children with the common genetic disorder neurofibromatosis type 1 (NF1) and plexiform neurofibromas, tolerated selumetinib and, in most cases, responded to it with tumor shrinkage. NF1 affects 1 in 3,000 people. The study results were published on December 29, 2016, in *The New England Journal of Medicine*. Selumetinib is being explored as a treatment option in registration-enabling studies in patients with NF1 and patients with differentiated thyroid cancer. Array licensed exclusive worldwide rights to selumetinib to AstraZeneca and is entitled to future potential milestones and royalties on product sales.

The trial, which included 24 patients recruited between September 2011 and February 2014, was led by the National Cancer Institute's Pediatric Oncology Branch. Plexiform neurofibromas develop in up to 50 percent of people with NF1. The majority of these tumors, which can cause significant pain, disability, and disfigurement, are diagnosed in early childhood and grow most rapidly prior to adolescence. Complete surgical removal of the tumors is rarely feasible, and incompletely resected tumors tend to grow back.

The primary aim of this clinical trial was to evaluate the toxicity and safety of selumetinib in patients with NF1 and inoperable plexiform neurofibromas, and, encouragingly, most of the selumetinib-related toxic effects were mild. At present, no therapies are considered effective for NF1-related large plexiform neurofibromas, but, in this trial, partial responses, meaning 20 percent or more reduction in tumor volume, were observed in over 70 percent of the patients.

Responses were observed in tumors that were previously growing at a rate of greater than 20 percent per year, as well as in non-progressing lesions. Tumor shrinkage was maintained long term, for approximately two years, and as of early 2016, no disease progression had been observed in any trial participant. Patients remained on study for as long as four years. Additionally, anecdotal evidence of clinical improvement, including a decrease in tumor-related pain, improvement in motor function, and decreased disfigurement, was reported.

FINANCIAL HIGHLIGHTS

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

- **Revenue** for the second quarter of fiscal 2017 was $44.5 million, compared to $39.3 million for the prior sequential quarter, mainly driven by earning a $6.0 million milestone from Loxo Oncology for the advancement of larotrectinib (LOXO-101), the pan-Trk inhibitor for cancer and a $2.5 million milestone from Roche for the advancement of danoprevir, the NS3/4A protease inhibitor for Hepatitis C.
- **Cost of partnered programs** for the second quarter of fiscal 2017 was $9.0 million, compared to $8.8 million for the prior quarter.
- **Research and development expense** was $46.5 million, compared to $46.6 million in the prior quarter.
- **Net loss** for the second quarter was $23.3 million, or ($0.14) per share, and was $28.6 million, or ($0.20) per share in the prior quarter. The decrease in net loss was primarily due to increased milestone revenue.
- **Cash, Cash Equivalents and Marketable Securities** as of December 31, 2016 were $214.8 million; this includes net proceeds of $124.2 million from the public offering of 21,160,000 shares of Array common stock in October 2016.

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

- **Revenue** for the second quarter of fiscal 2017 increased $9.1 million compared to the same quarter of fiscal 2016. The increase was primarily due to earning a milestone from Loxo Oncology for the advancement of larotrectinib (LOXO-101), the TRK inhibitor for cancer and a milestone from Roche for the advancement of danoprevir, the NS3 protease inhibitor for Hepatitis C.
- **Cost of partnered programs** increased $3.4 million compared to the second quarter of fiscal 2016. The increase was primarily due to costs incurred on the BEACON CRC trial.

- **Research and development expense** increased $5.1 million, compared to the second quarter of fiscal 2016. The increase was due to binimetinib and encorafenib expenses as we transitioned activity from the "Novartis Agreements."
- **Net loss** for the second quarter of fiscal 2017 was $23.3 million, or ($0.14) per share, and was $24.2 million, or ($0.17) per share, for the same quarter in fiscal 2016.

CONFERENCE CALL INFORMATION
Array will hold a conference call on Thursday, February 9, 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:	Thursday, February 9, 2017
Time:	9:00 a.m. Eastern Time
Toll-Free:	(844) 464-3927
Toll:	(765) 507-2598
Pass Code:	31445131

Webcast, including Replay and Conference Call Slides:
http://edge.media-server.com/m/p/x7g45956

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 cancer 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 February 9, 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 December 31,		Six Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenue				
Reimbursement revenue - Novartis	$ 27,948	$ 27,348	$ 59,269	$ 36,971
Collaboration revenue	6,030	6,977	12,319	13,551
License and milestone revenue	10,545	1,105	12,206	1,105
Total revenue	44,523	35,430	83,794	51,627
Operating expenses				
Cost of partnered programs	9,026	5,663	17,871	11,875
Research and development for proprietary programs	46,469	41,351	93,032	62,349
General and administrative	8,834	9,938	16,696	17,296
Total operating expenses	64,329	56,952	127,599	91,520
Loss from operations	(19,806)	(21,522)	(43,805)	(39,893)
Other income (expense)				

Impairment loss related to cost method investment	-	-	(1,500)	-
Interest income	212	51	282	91
Interest expense	(3,707)	(2,693)	(6,886)	(5,349)
Total other expense, net	(3,495)	(2,642)	(8,104)	(5,258)
Net loss	$ (23,301)	$ (24,164)	$ (51,909)	$ (45,151)
Net loss per share - basic	$ (0.14)	$ (0.17)	$ (0.33)	$ (0.32)
Net loss per share - diluted	$ (0.14)	$ (0.17)	$ (0.33)	$ (0.32)
Weighted average shares outstanding - basic	168,127	142,833	156,613	142,524
Weighted average shares outstanding - diluted	168,127	142,833	156,613	142,524

Summary Balance Sheet Data
(in thousands)

	December 31, 2016	June 30, 2016
Cash, cash equivalents and marketable securities	$ 214,754	$ 110,538
Working capital	$ 199,504	$ 102,867
Total assets	$ 272,202	$ 168,900
Long-term debt, net	$ 117,544	$ 113,655
Total stockholders' equity (deficit)	$ 52,052	$ (37,932)

CONTACT: Tricia Haugeto
(303) 386-1193
thaugeto@arraybiopharma.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/array-biopharma-reports-financial-results-for-the-second-quarter-of-fiscal-2017-300404833.html

SOURCE Array BioPharma