UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): June 27, 2018

Array BioPharma Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-16633**	**84-1460811**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

3200 Walnut Street, Boulder, Colorado 80301
(Address of principal executive offices, including Zip Code)

303 381-6600
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

In this report, "Array BioPharma," "Array," "we," "us" and "our" refer to Array BioPharma Inc., unless the context otherwise provides.

Item 7.01 Regulation FD Disclosure.

On June 27, 2018, the Company issued a press release, a copy of which is included as Exhibit 99.1 to this Form 8-K and incorporated herein by reference, relating to certain approval granted by the U.S. Food and Drug Administration ("FDA").

The information in this Item 7.01, including the press release included as Exhibit 99.1 to this Form 8-K, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities thereunder, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On June 27, 2018, the Company announced that the FDA has approved BRAFTOVI™ (encorafenib) capsules, for oral use, as well as MEKTOVI® (binimetinib) tablets, for oral use. MEKTOVI is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. BRAFTOVI is a kinase inhibitor indicated, in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test. BRAFTOVI is not indicated for the treatment of patients with wild-type BRAF melanoma.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 27, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 27, 2018

Array BioPharma Inc.

By: /s/ JASON HADDOCK
Jason Haddock
Chief Financial Officer

Array BioPharma Announces FDA Approval of BRAFTOVI™ (encorafenib) in Combination with MEKTOVI® (binimetinib)

– Approval based on Phase 3 COLUMBUS trial which demonstrated nearly 15 months median progression-free survival –

– BRAFTOVI + MEKTOVI now available for patients with advanced BRAF -mutant melanoma –

BOULDER, Colo., June 27, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) today announced that the U.S. Food and Drug Administration (FDA) has approved BRAFTOVI™ capsules in combination with MEKTOVI® tablets for the treatment of patients with unresectable or metastatic melanoma with a *BRAF*^{V600E} or *BRAF*^{V600K} mutation, as detected by an FDA-approved test. BRAFTOVI is not indicated for the treatment of patients with wild-type *BRAF* melanoma.

View original content with multimedia: https://www.multivu.com/players/English/8336151-array-biopharma-braftovi-mektovi-fda-approval/

"We are thrilled with the approval of BRAFTOVI + MEKTOVI, which help fill a critical unmet need for patients with advanced *BRAF*-mutant melanoma, a serious and deadly type of skin cancer," said Ron Squarer, Chief Executive Officer, Array BioPharma. "As presented at ASCO, BRAFTOVI + MEKTOVI is the first targeted treatment to demonstrate over 30 months median overall survival in a Phase 3 trial. These products represent a new standard of care for *BRAF*-mutant melanoma patients and we sincerely thank the patients and dedicated researchers who participated in our clinical program."

BRAFTOVI + MEKTOVI are now available to order through select specialty pharmacies in the U.S. market.

"Despite recent advances, there remains a significant unmet need for treatments that are both effective and well-tolerated for patients with *BRAF*-mutant melanoma," said Keith T. Flaherty, M.D., Director of the Termeer Center for Targeted Therapy, Massachusetts General Hospital Cancer Center and Professor of Medicine, Harvard Medical School. "Now, physicians and patients have the option to consider treatment with BRAFTOVI + MEKTOVI, which has been shown to delay disease progression, improve overall survival and is generally well-tolerated."

"Nearly half of patients diagnosed with metastatic melanoma test positive for the *BRAF* mutation," said Valerie Guild, Co-Founder and President of the AIM at Melanoma Foundation. "Today's approval is welcome news for the melanoma community as it arms *BRAF*-mutant late-stage melanoma patients with an important new targeted treatment in their fight against this devastating disease."

The approval of BRAFTOVI + MEKTOVI is based on results from the Phase 3 COLUMBUS trial, which demonstrated the combination doubled median progression-free survival (mPFS) compared to vemurafenib, alone (14.9 months versus 7.3 months, respectively [HR (0.54), (95% CI 0.41-0.71), p<0.0001]). Only 5% of patients who received BRAFTOVI + MEKTOVI discontinued treatment due to adverse reactions.

The most common adverse reactions (≥25%) in patients receiving BRAFTOVI + MEKTOVI were fatigue, nausea, diarrhea, vomiting, abdominal pain, and arthralgia.

As announced in February 2018, BRAFTOVI + MEKTOVI 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 the planned analysis of overall survival (OS) from the COLUMBUS trial. Median OS was 33.6 months for patients treated with the combination, compared to 16.9 months for patients treated with vemurafenib as a monotherapy. These positive results add to the growing body of clinical evidence supporting the BRAF/MEK inhibitor combination therapy and Array and its partners are working to formally submit these results with global regulatory authorities.

Array BioPharma is committed to providing access and reimbursement support to all patients. Array offers a $0 copay for eligible, commercially-insured patients. For more information about treatment of BRAFTOVI in combination with MEKTOVI, visit www.braftovimektovi.com.

The full prescribing information for BRAFTOVI can be found here:
http://www.arraybiopharma.com/documents/Braftovi_Prescribing_information.pdf

The full prescribing information for MEKTOVI can be found here:
http://www.arraybiopharma.com/documents/Mektovi_Prescribing_information.pdf

About *BRAF*-mutant Metastatic Melanoma

Melanoma develops when unrepaired DNA damage to skin cells triggers mutations that may lead them to multiply and form malignant tumors. Metastatic melanoma is the most serious and life-threatening type of skin cancer and is associated with low survival rates. [1, 2] There are a variety of gene mutations that can lead to metastatic melanoma. The most common genetic mutation in metastatic melanoma is *BRAF*. 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, 5]

About BRAFTOVI + MEKTOVI

BRAFTOVI is an oral small molecule BRAF kinase inhibitor and MEKTOVI is an oral small molecule MEK inhibitor which target key enzymes in the MAPK signaling pathway (RAS-RAF-MEK-ERK). Inappropriate activation of proteins in this pathway has been shown to occur in many cancers including melanoma, colorectal cancer, non-small cell lung cancer, thyroid and others. In the U.S., BRAFTOVI + MEKTOVI are approved for the treatment of unresectable or metastatic melanoma with a *BRAF*^{V600E} or *BRAF*^{V600K} mutation, as detected by an FDA-approved test. BRAFTOVI is not indicated for treatment of patients with wild-type BRAF melanoma.

Array has exclusive rights to BRAFTOVI and MEKTOVI 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.

BRAFTOVI + MEKTOVI are not approved outside of the U.S. The European Medicines Agency (EMA), as well as the Swiss Medicines Agency (Swissmedic) and the Australian Therapeutic Goods Administration (TGA), are currently reviewing the Marketing Authorization Applications submitted by Pierre Fabre, and Japan's Pharmaceuticals and Medical Devices Agency has accepted the Manufacturing and Marketing Approval applications submitted by Ono Pharmaceutical Co, Ltd.

About COLUMBUS

The COLUMBUS trial (NCT01909453) is a two-part, international, randomized, open label Phase 3 trial evaluating the efficacy and safety of BRAFTOVI (encorafenib) in combination with MEKTOVI (binimetinib) compared to vemurafenib and encorafenib monotherapy in 921 patients with locally advanced, unresectable or metastatic melanoma with *BRAF*^{V600} mutation. All secondary efficacy analyses, including overall survival, are descriptive in nature. Over 200 sites across North America, Europe, South America, Africa, Asia and Australia participated in the trial.

Indications and Usage

BRAFTOVI™ (encorafenib) and MEKTOVI® (binimetinib) are kinase inhibitors indicated for use in combination for the treatment of patients with unresectable or metastatic melanoma with a *BRAF*^{V600E} or *BRAF*^{V600K} mutation, as detected by an FDA-approved test.

Limitations of Use: BRAFTOVI is not indicated for the treatment of patients with wild-type *BRAF* melanoma.

BRAFTOVI + MEKTOVI Important Safety Information

The information below applies to the safety of the combination of BRAFTOVI and MEKTOVI unless otherwise noted.

Warnings and Precautions

New Primary Malignancies: New primary malignancies, cutaneous and non-cutaneous malignancies can occur. In the COLUMBUS trial, cutaneous squamous cell carcinoma, including keratoacanthoma, occurred in 2.6% and basal cell carcinoma occurred in 1.6% of patients. Perform dermatologic evaluations prior to initiating treatment, every 2 months during treatment, and for up to 6 months following discontinuation of treatment. Discontinue BRAFTOVI for *RAS* mutation-positive non-cutaneous malignancies.

Tumor Promotion in *BRAF* Wild-Type Tumors: Confirm evidence of *BRAF*^{V600E} or *BRAF*^{V600K} mutation prior to initiating BRAFTOVI.

Cardiomyopathy: In the COLUMBUS trial, cardiomyopathy occurred in 7% and Grade 3 left ventricular dysfunction occurred in 1.6% of patients. Cardiomyopathy resolved in 87% of patients. Assess left ventricular ejection fraction by echocardiogram or MUGA scan prior to initiating treatment, 1 month after initiating treatment, and then every 2 to 3 months during treatment. The safety has not been established in patients with a baseline ejection fraction that is either below 50% or below the institutional lower limit of normal.

Venous Thromboembolism (VTE): In the COLUMBUS trial, VTE occurred in 6% of patients, including 3.1% of patients who developed pulmonary embolism.

Hemorrhage: In the COLUMBUS trial, hemorrhage occurred in 19% of patients and ≥Grade 3 hemorrhage occurred in 3.2% of patients. Fatal intracranial hemorrhage in the setting of new or progressive brain metastases occurred in 1.6% of patients.

Ocular Toxicities: In the COLUMBUS trial, serous retinopathy occurred in 20% of patients; 8% were retinal detachment and 6% were macular edema. Symptomatic serous retinopathy occurred in 8% of patients with no cases of blindness. In patients with *BRAF* mutation-positive melanoma across multiple clinical trials, 0.1% of patients experienced retinal vein occlusion (RVO). Permanently discontinue MEKTOVI in patients with documented RVO. In COLUMBUS, uveitis, including iritis and iridocyclitis, was reported in 4% of patients. Assess for visual symptoms at each visit. Perform ophthalmic evaluation at regular intervals and for any visual disturbances.

Interstitial Lung Disease (ILD): ILD, including pneumonitis, occurred in 0.3% of patients with *BRAF* mutation-positive melanoma across multiple clinical trials. Assess new or progressive unexplained pulmonary symptoms or findings for possible ILD.

Hepatotoxicity: In the COLUMBUS trial, the incidence of Grade 3 or 4 increases in liver function laboratory tests was 6% for alanine aminotransferase (ALT) and 2.6% for aspartate aminotransferase (AST). Monitor liver laboratory tests before and during treatment and as clinically indicated.

Rhabdomyolysis: In the COLUMBUS trial, elevation of laboratory values of serum creatine phosphokinase (CPK) occurred in 58% of patients. Rhabdomyolysis was reported in 0.1% of patients with *BRAF* mutation-positive melanoma across multiple clinical trials. Monitor CPK periodically and as clinically indicated.

QTc Prolongation: In the COLUMBUS trial, an increase in QTcF to >500 ms was measured in 0.5% (1/192) of patients. Monitor patients who already have or who are at significant risk of developing QTc prolongation. Correct hypokalemia and hypomagnesemia prior to and during BRAFTOVI administration. Withhold, reduce dose, or permanently discontinue for QTc >500 ms.

Embryo-Fetal Toxicity: BRAFTOVI or MEKTOVI can cause fetal harm when administered to pregnant women. Nonhormonal contraceptives should be used during treatment and for at least 30 days after the final dose for patients taking BRAFTOVI + MEKTOVI.

Adverse Reactions

The most common adverse reactions (≥20%, all Grades, in the COLUMBUS trial) were: fatigue, nausea, diarrhea, vomiting, abdominal pain, arthralgia, myopathy, hyperkeratosis, rash, headache, constipation, visual impairment, serous retinopathy.

In the COLUMBUS Trial, the most common laboratory abnormalities (≥20%, all Grades) included: increased creatinine, increased CPK, increased gamma glutamyl transferase, anemia, increased ALT, hyperglycemia, increased AST, and increased alkaline phosphatase.

Drug interactions

Avoid concomitant use of strong or moderate CYP3A4 inhibitors or inducers and sensitive CYP3A4 substrates with BRAFTOVI. Modify BRAFTOVI dose if concomitant use of strong or moderate CYP3A4 inhibitors cannot be avoided.

Please see full Prescribing Information for BRAFTOVI and full Prescribing Information for MEKTOVI for additional information. You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Array at 1-844-Rx-Array (1-844-792-7729).

About Array BioPharma

Array BioPharma Inc. is a fully-integrated, biopharmaceutical company focused on the discovery, development and commercialization of safe and effective targeted small molecule drugs to treat patients afflicted with cancer and other conditions. Array markets in the United States BRAFTOVI™ (encorafenib) capsules in combination with MEKTOVI® (binimetinib) tablets for the treatment of patients with unresectable or

metastatic melanoma with a *BRAF*^{V600E} or *BRAF*^{V600K} mutation. Array's lead clinical programs, encorafenib and binimetinib, are being investigated in over 30 clinical trials across a number of solid tumor indications, including a Phase 3 trial in *BRAF*-mutant colorectal cancer. Array's pipeline includes several additional advanced programs including selumetinib (partnered with AstraZeneca), larotrectinib (partnered with Loxo Oncology), ipatasertib (partnered with Genentech), tucatinib (partnered with Seattle Genetics) and ARRY-797 (being developed by Yarra Therapeutics, a wholly-owned subsidiary of Array), all of which are currently in registration trials. Ganovo® (danoprevir, partnered with Roche) was recently approved in China for the treatment of viral hepatitis C. For more information on Array, please visit www.arraybiopharma.com or follow @arraybiopharma on Twitter and LinkedIn.

References

[1] Melanoma Skin Cancer. American Cancer Society. Available at: https://www.cancer.org/cancer/melanoma-skin-cancer.html. Accessed January 2018.

[2] A Snapshot of Melanoma. National Cancer Institute. Available at: https://seer.cancer.gov/statfacts/html/melan.html. Accessed January 2018.

[3] Globocan 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. http://globocan.iarc.fr/Pages/fact_sheets_population.aspx. Accessed January 2018.

[4] Klein O, et al. *Eur J Cancer*, 2013.

[5] American Cancer Society. What Causes Melanoma Skin Cancer? 2016. https://www.cancer.org/cancer/melanoma-skin-cancer/causes-risks-prevention/what-causes.html. Accessed April 11, 2018.

[6] BRAFTOVI™ (encorafenib) Prescribing Information. Array BioPharma Inc., June 2018

[7] MEKTOVI® (binimetinib) Prescribing Information. Array BioPharma Inc., June 2018

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, among others, statements about the future development plans of encorafenib and binimetinib; expectations that events will occur that will create 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. Because these statements reflect our current expectations concerning future events and involve significant risks and uncertainties, 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 potential that the FDA, EMA or other regulatory agencies determine 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. Additional information concerning these and other risk factors can be found 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. We are providing this information as of June 27, 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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