Array BioPharma Announces Oral Presentation from the Pivotal Phase 3 COLUMBUS trial of the Combination of Encorafenib and Binimetinib in Patients with BRAF-mutant Melanoma at 2018 ASCO Annual Meeting

May 16, 2018

- Oral presentation and encore investor webcast presentation June 4, 2018 -

BOULDER, Colo., May 16, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) announced that it will present data from the Phase 3 COLUMBUS trial of encorafenib and binimetinib in advanced *BRAF*-mutant melanoma in an oral presentation on June 4, 2018, at the 54th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois.

"Binimetinib and encorafenib is the first targeted therapy to demonstrate over 30 months median overall survival in a Phase 3 trial and we look forward to presenting the results from the COLUMBUS trial at ASCO," said Ron Squarer, Chief Executive Officer. "With nearly 15 months median progression-free survival and an attractive tolerability profile, these data underscore the potential of this combination to become an important new treatment option for patients with *BRAF*-mutant advanced, unresectable or metastatic melanoma."

As previously announced, the most common Grade 3/4 adverse events (AEs) seen in more than 5% of patients were increased gamma-glutamyltransferase (GGT) (9%), increased creatine phosphokinase (7%), and hypertension (6%) in the encorafenib plus binimetinib group.

Oral Presentation:

Title:	Overall Survival in COLUMBUS: A Phase 3 Trial of Encorafenib (ENCO) Plus Binimetinib (BINI) vs Vemurafenib (VEM) or ENCO in *BRAF*-Mutant Melanoma
Presenter:	Reinhard Dummer, M.D.
Abstract:	Abstract #223875/Publication #9504
Session:	Melanoma/Skin Cancers
Date:	Monday, June 4, 2018
Time:	9:12 a.m. - 9:24 a.m. Central Time (10:12 a.m. – 10:24 a.m. Eastern Time)
Location:	Arie Crown Theater

The abstract can be accessed through the ASCO website, http://abstract.asco.org/, beginning May 16, 2018, at 5:00 p.m. Eastern Time. Following the presentation on June 4, the slides will be available as a PDF on Array's website at www.arraybiopharma.com.

Array will host an encore webcast presentation of the COLUMBUS trial data.

Encore Webcast:

Date:	Monday, June 4, 2018
Time:	11:15 a.m. Central Time (12:15 p.m. Eastern Time)
Toll-Free:	(844) 464-3927
Toll:	(765) 507-2598
Pass Code:	9615719

Webcast, including replay and conference call slides:https://edge.media-server.com/m6/p/8juh6tcn

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 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 the combination of encorafenib 450 mg daily and binimetinib 45 mg twice daily (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 published in *The Lancet Oncology* May 2018, 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 daily 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 Encorafenib and Binimetinib
BRAF and MEK are key protein kinases in the MAPK signaling pathway (RAS-RAF-MEK-ERK). Research has shown this pathway regulates several key cellular activities including proliferation, differentiation, survival and angiogenesis. Inappropriate activation of proteins in this pathway has been shown to occur in many cancers including melanoma and colorectal cancer. Encorafenib is a late-stage small molecule BRAF inhibitor and binimetinib is a late-stage small molecule MEK inhibitor, both of which target key enzymes in this pathway. Encorafenib and binimetinib are being studied in clinical trials in advanced cancer patients, including the Phase 3 COLUMBUS trial and the Phase 3 BEACON CRC trial.

Array BioPharma has exclusive rights to encorafenib and binimetinib 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. Encorafenib and binimetinib are investigational medicines and are not currently approved in any country.

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
[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.

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