Array BioPharma to Present Overall Survival Results from the Phase 3 BEACON CRC Safety Lead-In of the Combination of Encorafenib, Binimetinib and Cetuximab in BRAF-Mutant Colorectal Cancer at the ESMO 20th World Congress on Gastrointestinal Cancer

June 18, 2018

- Encore investor webcast presentation June 23, 2018 -

BOULDER, Colo., June 18, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) announced that it will present updated safety and efficacy results, including overall survival (OS) data, from the safety lead-in of the Phase 3 BEACON CRC trial evaluating the triplet combination of encorafenib, a BRAF inhibitor, binimetinib, a MEK inhibitor and cetuximab, an anti-EGFR antibody, in patients with *BRAF*-mutant colorectal cancer (CRC). These data will be featured in an oral presentation on Saturday, June 23, at the ESMO 20thWorld Congress on Gastrointestinal Cancer in Barcelona, Spain.

Oral Presentation BEACON CRC Safety Lead-In

Title:	BEACON CRC Study Safety Lead-in: Assessment of the BRAF Inhibitor Encorafenib + MEK Inhibitor Binimetinib + Anti–Epidermal Growth Factor Receptor Antibody Cetuximab for *BRAF*^{V600E} Metastatic Colorectal Cancer
Presenter:	Eric Van Cutsem, M.D., Professor, Internal Medicine, Head, Digestive Oncology Unit, University Hospital Gasthuisberg, Leuven
Abstract:	O-027
Session:	Session XX
Date:	Saturday, June 23
Session Time:	11:40 a.m. – 12:20 p.m. CET (5:40 – 6:20 a.m. ET)
Location:	Auditorium A

Following the presentation, 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 BEACON CRC safety lead-in trial data.

Encore Investor Webcast:

Presenter:	Axel Grothey, M.D., Division of Hematology/Oncology, Mayo Clinic
Date:	Saturday, June 23
Time:	4:30 pm CET (10:30 am ET)
Toll-Free:	(844) 464-3927
Toll:	(765) 507-2598
Pass Code:	8588348

Webcast, including replay and conference call slides:https://edge.media-server.com/m6/p/bn2j2g45

About Colorectal Cancer
Worldwide, colorectal cancer 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. Globally in 2012, approximately 694,000 deaths were attributed to colorectal cancer. [1] 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. [2] In the U.S., *BRAF* mutations are estimated to occur in 10% to 15% of patients with colorectal cancer and represent a poor prognosis for these patients. [3, 4, 5, 6] The risk of mortality in CRC patients with the *BRAF*^{V600E} mutation is more than two times higher than for those with wild-type *BRAF*. [7] Several approved standard of care benchmarks for this population range between 4% to 8% ORR, 1.8 and 2.5 months mPFS and 4 and 6 months mOS. [8, 9, 10, 11, 12, 13, 14] 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. [8]

About BEACON 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. BEACON CRC is the first and only Phase 3 trial designed to test a BRAF/MEK combo targeted therapy in *BRAF*-mutant advanced CRC. Thirty patients were treated in the safety lead-in and received the triplet combination (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 overall survival 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 is being conducted at over 200 investigational sites in North America, South America, Europe and the Asia Pacific region. Patient enrollment is expected to be completed in 2018.

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 BEACON CRC trial and the Phase 3 COLUMBUS trial.

The U.S. Food and Drug Administration (FDA) is currently reviewing the New Drug Applications (NDAs) to support use of the combination of encorafenib and binimetinib for the treatment of patients with *BRAF*$^{V600E\ or\ K}$-mutant advanced, unresectable or metastatic melanoma. The FDA set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 30, 2018 for both applications. 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.

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

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. The BEACON CRC trial is being conducted with support from Pierre Fabre and Merck KGaA, Darmstadt, Germany (support is for sites outside of North America).

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. 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] Global Cancer Facts & Figures 3rd Edition. American Cancer Society. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/global-cancer-facts-and-figures/global-cancer-facts-and-figures-3rd-edition.pdf. Accessed January 2018.
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