Array BioPharma Announces Strategic Collaboration with Pfizer

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Novel combinations of binimetinib (MEK), avelumab (PD-L1), and talazoparib (PARP inhibitor) to be studied across tumor types

BOULDER, Colo., Dec. 19, 2017 /PRNewswire/ -- Array BioPharma (Nasdaq: ARRY) announced today that it has entered into a clinical trial collaboration agreement with Pfizer to investigate the safety and efficacy of several novel anti-cancer combinations, including Array's MEK inhibitor, binimetinib, with Pfizer's investigational PARP inhibitor talazoparib, and avelumab*, a human anti-PD-L1 IgG1 monoclonal antibody.

The companies are entering into this collaboration to explore the potential benefits of combining molecularly targeted therapeutics with the body's innate cancer-fighting abilities using immunotherapy.

"Array is excited to announce this partnership with Pfizer, an established global leader in Oncology therapeutics," said Ron Squarer, Chief Executive Officer, Array BioPharma. "These novel approaches combining targeted therapy and immunotherapy hold great potential to help patients fighting cancer in different indications, with an initial main focus on lung and pancreatic cancer."

"Preclinical data indicate that combining binimetinib with an immune checkpoint inhibitor and talazoparib could be a rational combination to test in the clinic," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-Oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "We are looking forward to initiating the clinical studies with Array BioPharma to explore anti-tumor activity across various novel combination strategies, including both doublet and triplet approaches."

Under the terms of the agreement, Array and Pfizer will collaborate on a Phase 1b clinical trial to explore a series of novel combinations, investigating the safety and efficacy of the combination of binimetinib, avelumab and talazoparib across various tumor types. A multi-arm clinical trial is expected to establish recommended doses of different regimens combining the drugs. Initially the focus will be in non-small cell lung cancer (NSCLC) and pancreatic cancer, and additional indications will be explored at a later stage. The study is expected to begin by the third quarter of 2018, and results will be used to determine optimal approaches to further clinical development of these combinations.

Under the collaboration agreement, the trial will be sponsored and funded by Pfizer, with Array providing binimetinib supply.

*Avelumab is jointly developed by Merck KGaA, Darmstadt, Germany and Pfizer. Avelumab is under clinical investigation for treatment of NSCLC and pancreatic cancer and has not been demonstrated to be safe and effective for these indications. There is no guarantee that avelumab will be approved for these indications by any health authority worldwide.

About Binimetinib

MEK is a key protein kinase 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, such as melanoma, colorectal and thyroid cancers. Binimetinib is a late-stage, small molecule MEK inhibitor which targets key enzymes in this pathway. Binimetinib is an investigational medicine and is not currently approved in any country.

Binimetinib is being studied in clinical trials in advanced cancer patients, including the Phase 3 COLUMBUS trial in patients with BRAF-mutant melanoma and the Phase 3 BEACON CRC trial in patients with *BRAF V600E*-mutant colorectal cancer.

About Avelumab

Avelumab is a human anti-programmed death ligand-1 (PD-L1) antibody. Avelumab has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, avelumab has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models. Avelumab has also been shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Avelumab is currently being evaluated in the JAVELIN clinical development program, which involves at least 30 clinical programs, including nine Phase III trials, and more than 7,000 patients across more than 15 different tumor types, including gastric/gastroesophageal junction, non-small cell lung cancer, renal cell carcinoma and ovarian cancer. For a comprehensive list of all avelumab trials, please visit clinicaltrials.gov.

Indications in the US

The FDA granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information from the US FDA Approved Label

The warnings and precautions for BAVENCIO include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO for mMCC and patients with locally advanced or metastatic UC include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com.

About Talazoparib
Talazoparib is an investigational anti-cancer compound called a PARP (poly ADP ribose polymerase) inhibitor. Preclinical studies suggest that talazoparib is highly potent and has a dual mechanism of action, with the potential to induce tumor cell death by blocking PARP enzyme activity and trapping PARP on the sites of DNA damage. Talazoparib is currently being evaluated in advanced germline (inherited) BRCA+ breast cancer as well as other cancer types with deficiencies in DNA damage repair (DDR). Talazoparib has not been approved by any regulatory authorities for the treatment of any disease.

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. Nine registration studies are currently advancing related to seven Array-owned or partnered drugs: binimetinib (MEK162), encorafenib (LGX818), selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Cascadian Therapeutics).

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 statements about the timing of the commencement of the binimetinib, *BAVENCIO and talazoparib* clinical trial; expectations that events will occur relating to this collaboration that will result in greater value for Array; and the potential for the results of the planned clinical trial to support regulatory approval or the marketing success of the combination. 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, the determination by the FDA that results from planned clinical trial are not sufficient to support registration or marketing approval of binimetinib and encorafenib; Pfizer's 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; and risks associated with a dependence on third-party service providers to successfully conduct clinical trials within and outside the United States. We are providing this information as of December 19, 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.

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