

Array BioPharma Announces Strategic Collaboration with Merck

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- Novel combinations of binimetinib (MEK inhibitor) and KEYTRUDA® (pembrolizumab, anti-PD-1 therapy) to be studied in colorectal cancer patients with microsatellite stable tumors -

BOULDER, Colo., May 8, 2017 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) announced today that it has entered into a clinical trial collaboration agreement with Merck (known as MSD outside the United States and Canada) to investigate the safety and efficacy of Array's MEK inhibitor, binimetinib, with Merck's anti-PD-1 therapy, KEYTRUDA[®] (pembrolizumab), in metastatic colorectal cancer patients with microsatellite stable tumors (MSS CRC).



The companies are entering into this collaboration based on the growing body of preclinical and clinical evidence that the immune activity of an anti-PD-1 therapy, such as KEYTRUDA, can be enhanced when combined with a MEK inhibitor, such as binimetinib.

"Array is excited to announce this partnership with Merck, an established leader in the field of immuno-oncology," said Ron Squarer, Chief Executive Officer, Array BioPharma. "Given the synergistic activity we have seen with our MEK inhibitor when combined with anti-PD-1 therapy in preclinical models, and based on emerging clinical data, we are optimistic that this combination holds great potential for cancer patients."

Under the terms of the agreement, Array and Merck will collaborate on a clinical trial to investigate the safety and efficacy of the combination of binimetinib with KEYTRUDA, in MSS CRC patients. The trial is expected to establish a recommended dose regimen of binimetinib and KEYTRUDA, as well as explore the preliminary anti-tumor activity of several novel regimens. The study is expected to begin in the second half of 2017. Results from this first study will be used to determine optimal approaches to further clinical development of these combinations.

The collaboration agreement is between Array BioPharma and Merck, through a subsidiary. Under the agreement, the trial will be sponsored by Merck. Additional details of the collaboration were not disclosed.

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. Of these, nearly 750,000 were diagnosed in men, and 614,000 in women. Globally in 2012, approximately 694,000 deaths were attributed to colorectal cancer. In the U.S. alone, an estimated 135,430 patients will be diagnosed with cancer of the colon or rectum in 2017, and approximately 50,000 are estimated to die of their disease. There is wide variation in 5-year survival rates across the globe, with 5-year survival expected to be around 65% in the developed world and dropping to around 20% in some developing countries. The incidence of microsatellite stability in colorectal tumors varies by stage, with nearly 80% of early stage, resectable tumors and approximately 67% of advanced, metastatic tumors exhibiting MSS.

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

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 and KEYTRUDA clinical trial; expectations that events will occur 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 clinical trials are not sufficient to support registration or marketing approval of binimetinib and encorafenib; risks associated with our dependence on third-parties to successfully conduct clinical trials within and outside the United States; our ability to achieve and maintain profitability and maintain sufficient cash resources; and our ability to attract and retain experienced scientists and management. We are providing this information as of April 8, 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.

 ${\sf KEYTRUDA}^{\circledR} \ is \ a \ registered \ trademark \ of \ Merck \ Sharp \ \& \ Dohme \ Corp., \ a \ subsidiary \ of \ Merck \ \& \ Co., \ Inc., \ Kenilworth, \ NJ, \ USA$

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