



Array BioPharma Reports Initial Results From Novel Immunotherapy Combination At The Society For Immunotherapy Of Cancer (SITC) 32nd Annual Meeting

November 13, 2017

- **ARRY-382 (CSF1R inhibitor) demonstrated initial signs of clinical activity when combined with KEYTRUDA® (anti-PD1 antibody) immunotherapy in patients with solid tumors -**
- **Array plans to expand ongoing Phase 2 CSF1R + PD1 combination study into other tumor types including pancreatic cancer -**

BOULDER, Colo., Nov. 13, 2017 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY), a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule cancer therapies, today announced data from the Phase 1b clinical trial evaluating the immunotherapy combination of ARRY-382, with Merck's KEYTRUDA® (pembrolizumab), an anti-PD-1 antibody, in patients with certain advanced solid tumors, at the [Society for Immunotherapy of Cancer \(SITC\) 32nd Annual Meeting](#), being held Nov. 8-12, 2017 in National Harbor, Maryland. ARRY-382 is a highly selective oral inhibitor of the CSF1R kinase and would be among the first investigational compounds targeting this pathway.



"We are pleased to announce completion of the Phase 1b clinical study of ARRY-382 in combination with KEYTRUDA. In addition to establishing an appropriate Phase 2 dose for the combination, we are encouraged by the early signs of activity in patients with tumor types that have been historically unresponsive to anti-PD1 therapies," said Ron Squarer, Chief Executive Officer, Array BioPharma.

In the Phase 1b dose escalation trial, the recommended Phase 2 dose of ARRY-382 was determined to be 300 mg daily in combination with KEYTRUDA 2 mg/kg given intravenously every 3 weeks.

Nineteen patients, with a median of two prior lines of therapy and 42% with ≥ 3 prior regimens, were treated in the study. Patients with pancreatic (n=6), colorectal (n=5), ovarian (n=3), gastric and melanoma (n=2, each), and triple negative breast cancer (n=1) were enrolled. Investigators noted that ARRY-382 had a manageable safety profile when administered with KEYTRUDA in this study, and the most common grade 3/4 adverse events (AEs) (>10%), regardless of causality, included increased AST, increased blood creatine kinase (CK), rash, increased lipase, increased alkaline phosphatase (ALP), increased alanine aminotransferase (ALT) and anemia.

The combination of ARRY-382 and KEYTRUDA demonstrated early signs of activity, with 11% (n=2) of patients achieving a confirmed partial response, based on RECIST version 1.1 guidelines. The first responder, who was treated with ARRY-382 at 200 mg, had Stage III pancreatic ductal adenocarcinoma. As of the data cut-off, this patient was on study treatment in cycle 14 (42 weeks). The second responder, who was treated with ARRY-382 at 300 mg, had stage IV ovarian cancer with liver metastasis. As of the data cut-off, this patient was on study treatment in cycle 8 (24 weeks).

The current trial was designed to enroll Phase 2 cohorts in both melanoma and non-small cell lung cancer patients, and now Array plans to expand the study to include other patient populations, including a cohort of pancreatic cancer patients. The Phase 2 portion of the study is currently active and enrolling patients.

About CSF1R and ARRY-382

Colony-stimulating factor 1 receptor (CSF1R) is a cell-surface receptor for its ligands, colony-stimulating factor 1 (CSF1) and IL-34.[1, 2] CSF1R is thought to play an important role as regulator of the development, morphology, survival, and functions of tissue macrophages as well as tumor-associated macrophages (TAMs). TAMs play a role in modulating anti-tumor adaptive immunity and CSF1 is believed to be a driver of TAM differentiation towards an immunosuppressive tumor promoting phenotype. Increased CSF1 expression is implicated in tumor progression and metastasis, and is associated with poor prognosis in some cancers.[3] Combining a PD-1 inhibitor with a CSF1R inhibitor in preclinical models shows enhanced antitumor activity. ARRY-382 is a highly selective, oral inhibitor of CSF1R.

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).

References

1. Pixley FJ, Stanley ER. Trends Cell Biol. 2004;14(11):628-638.
2. Lin H, et al. Science. 2008;320(5877):807-811.
3. Aharinejad S, et al. Cancer Res. 2004;64(15):5378-5384.

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 announcement of the results of clinical trials for our proprietary and our partnered programs, the timing of the completion or initiation of further development of our wholly-owned and our partnered programs, including the timing of regulatory filings or approvals, expectations that events will occur that will result in greater value for Array, the potential for the results of ongoing preclinical and clinical trials to support regulatory approval or the marketing success of a drug candidate, our ability to partner our proprietary drug candidates for up-front fees, milestone and/or royalty payments, our future plans to progress and develop our proprietary programs, our future capital requirements and the plans of our collaborators to progress and develop programs we have licensed to them, and our plans to build a commercial-stage biopharmaceutical company. 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, our ability to continue to fund and successfully progress internal research and development efforts and to create effective, commercially-viable drugs; risks relating to the regulatory approval process for our drug candidates, which may not result in approval for our drug candidates, cause delays in development or require that we expend more resources to obtain approval than expected; risks associated with our dependence on our collaborators for the clinical development and commercialization of our out-licensed drug candidates; the ability of our collaborators and of Array to meet objectives tied to milestones and royalties; 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 within and outside the United States; our ability to achieve and maintain profitability and maintain sufficient cash resources; the extent to which the pharmaceutical and biotechnology industries are willing to in-license drug candidates for their product pipelines and to collaborate with and fund third parties on their drug discovery activities; our ability to out-license our proprietary candidates on favorable terms; and our ability to attract and retain experienced scientists and management. We are providing this information as of November 13, 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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