Arcus Biosciences to Present Preliminary Data from Phase 1 Portion of ARC-8 Study for AB680 in Metastatic Pancreatic Cancer at ASCO-GI Symposium

1/11/2021

- Preliminary data from the first dose-escalation cohorts, reported in an abstract released today, demonstrate encouraging signs of clinical activity for AB680 in combination with zimberelimab (anti-PD-1 antibody) and chemotherapy

- Additional data, as of a cut-off date of December 9, 2020, to be presented at ASCO-GI on January 15th

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), an oncology-focused biopharmaceutical company working to create best-in-class cancer therapies, today announced that preliminary data from the ongoing dose-escalation portion of its ARC-8 Phase 1/1b study, evaluating the safety and tolerability of AB680, the first small-molecule CD73 inhibitor to enter the clinic, in combination with zimberelimab (anti-PD-1) and nab-paclitaxel plus gemcitabine (chemotherapy) in front-line metastatic pancreatic cancer will be presented in a poster session at the ASCO 2021 Virtual Gastrointestinal Cancers Symposium (ASCO GI) being held January 15th – 17th, 2021.

“While recent cancer breakthrough therapies, most notably anti-PD-1 antibodies, have led to dramatic improvements in outcomes in many cancer settings, this is not the case for pancreatic cancer, which remains a devastating diagnosis for patients. We are highly encouraged by the preliminary data from our Phase 1 trial for AB680 in combination with anti-PD-1 therapy and chemotherapy, in which we have seen promising clinical activity in these difficult to treat patients. Importantly, this experimental regimen has been well tolerated, and early safety data indicate that this AB680 combination regimen appears to have a side effect profile similar to that of anti-PD-1 therapy and chemotherapy,” said Bill Grossman, M.D., the Chief Medical Officer of Arcus. “We look forward to
presenting updated data from the Phase 1 portion of this trial at ASCO GI on January 15th, wherein we will report more mature safety and clinical response data, including those from the 100mg dose cohort.”

The clinical activity and safety profile observed to date with AB680 in combination with zimberelimab (anti-PD-1 antibody) and chemotherapy support its recent advancement into the ongoing Phase 1b expansion portion of the study, as well as plans to open a randomized control arm for the Phase 1b expansion. Dosing of AB680 100mg I.V. every two weeks has been selected for this portion of the study.

**Full details of the presentation are as follows:**

Abstract/Poster Title: ARC-8: Phase I/Ib study to evaluate safety and tolerability of AB680 + chemotherapy + zimberelimab (AB122) in patients with treatment-naive metastatic pancreatic adenocarcinoma (mPDAC)
Abstract No: 404
Poster Session: Pancreatic Cancer
Available Date: January 15, 2021
Time: 5:00 a.m. PT

In addition to the presentation on AB680, Arcus will also highlight the design of the recently initiated ARC-9 randomized Phase 2 study to advance etrumadenant in late-line colorectal cancer:

Abstract/Poster Title: ARC-9: Phase Ib/II study to evaluate etrumadenant (AB928)-based treatment combinations in patients with metastatic colorectal cancer (mCRC)
Abstract No: TPS150
Trials in Progress Poster Session: Colorectal Cancer
Available Date: January 15, 2021
Time: 5:00 a.m. PT

**Pancreatic Cancer**

Pancreatic cancer is the fourth leading cause of cancer-related deaths in Europe and the United States and the seventh leading cause of cancer-related deaths worldwide.

Pancreatic ductal adenocarcinoma (PDAC) is the most prevalent neoplastic disease of the pancreas, with high metastatic potential, accounting for more than 90% of all pancreatic malignancies and is a highly devastating disease with poor prognosis and rising incidence.

Few treatment options exist for metastatic pancreatic cancer, and response rates to the standard of care therapy of
gemcitabine/nab-paclitaxel remain very low. Based on the FDA approved label for nab-paclitaxel in combination with gemcitabine, the phase 3 registrational trial demonstrated overall and complete response rates in patients with metastatic pancreatic cancer that were 23% and <1%, respectively. 1,5

To date, addition of anti-PD-1 antibodies to gemcitabine/nab-paclitaxel in controlled clinical trials in this setting has shown no added benefit when compared to that obtained with the chemotherapy alone.6,7

About ARC-8 Study

ARC-8 is a Phase 1/1b study to evaluate safety and tolerability of AB680 + zimberelimab (AB122) + chemotherapy in patients with treatment-naive metastatic pancreatic adenocarcinoma.

For additional information on this trial (NCT04104672), please visit www.clinicaltrials.gov.

About AB680

AB680 is an extremely potent and selective small-molecule CD73 inhibitor designed to provide differential benefits relative to monoclonal antibodies, such as greater inhibition of CD73 enzymatic activity (both soluble and cell-bound) and deeper tumor penetration. CD73 is the primary enzymatic producer of immunosuppressive adenosine in the tumor microenvironment, and high CD73 expression is associated with significantly poorer prognosis in several tumor types, including pancreatic cancer. 8 By effectively eliminating CD73-derived adenosine, AB680 may improve the efficacy of treatment approaches expected to elicit anti-cancer immune responses (e.g., platinum-based chemotherapy with/without anti-PD-1 therapy). AB680 was the first small-molecule CD73 inhibitor to enter the clinic and demonstrated a favorable safety profile with a long half-life in a healthy volunteer study. AB680 is currently in a Phase 1/1b study for the treatment of first-line metastatic pancreatic cancer.

About Arcus Biosciences

Arcus Biosciences is an oncology-focused biopharmaceutical company leveraging its deep cross-disciplinary expertise to discover highly differentiated therapies and to develop a broad portfolio of novel combinations addressing significant unmet needs. Arcus currently has four molecules in clinical development: Etrumadenant (AB928), the first and only dual A2a/A2b adenosine receptor antagonist in the clinic, is being evaluated in multiple Phase 2 and 1b studies across different indications, including prostate, colorectal, non-small cell lung, pancreatic and triple-negative breast cancers. AB680, the first small-molecule CD73 inhibitor to enter the clinic, is in Phase 1/1b development for first-line treatment of metastatic pancreatic cancer in combination with zimberelimab and gemcitabine/nab-paclitaxel. Domvanalimab (AB154), an anti-TIGIT monoclonal antibody and new potential immuno-oncology backbone therapy, is in a three-arm randomized Phase 2 study for first-line treatment of PD-L1-
high metastatic non-small cell lung cancer evaluating zimberelimab monotherapy, AB154 with zimberelimab and AB154 plus AB928 with zimberelimab. Zimberelimab (AB122), Arcus’s anti-PD-1 monoclonal antibody, is also being evaluated in a Phase 1b study as monotherapy for cancers with no approved anti-PD-1 treatment options, and in various combinations across the portfolio. For more information about Arcus Biosciences, please visit www.arcusbio.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including, but not limited to, Arcus's development plans for AB680, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or implied. Factors that could cause or contribute to such differences include, but are not limited to: risks associated with preliminary and interim data; the emergence of adverse events or other undesirable side effects; delays in our clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; and the inherent uncertainty associated with pharmaceutical product development and clinical trials. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended September 30, 2020 filed on November 5, 2020 with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Arcus disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

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References


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