



## NEWS RELEASE

# Arcus Biosciences Presents Early Data from ARC-6, a Phase 1b/2 Study Evaluating Etrumadenant-Based Combinations in Metastatic Castrate-Resistant Prostate Cancer at the 2021 ASCO Annual Meeting

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- In this first reported Phase 1b cohort, the etrumadenant-based combination was well tolerated with a composite overall response rate (ORR) of 41% in people previously treated for metastatic castrate-resistant prostate cancer (mCRPC)
- Etrumadenant is the first dual adenosine A2a/A2b receptor antagonist to demonstrate evidence of clinical activity in prostate cancer
- Data provide further support for the potential role of adenosine receptor blockade in the treatment of certain cancer types, particularly in those that are considered to be non-responsive to anti-PD-(L)1 therapy

HAYWARD, Calif.--(BUSINESS WIRE)-- **Arcus Biosciences, Inc.** (NYSE:RCUS), an oncology-focused biopharmaceutical company working to create best-in-class cancer therapies, today announced initial efficacy and safety data from one of the cohorts in ARC-6, a randomized Phase 1b/2 platform study, evaluating the novel combination of etrumadenant (dual adenosine A2a/A2b receptor antagonist) plus zimberelimab (anti-PD1 antibody) and docetaxel in people with taxane-naïve mCRPC who progressed following treatment with one or more new hormonal agents and were checkpoint inhibitor-naïve. In this Phase 1b cohort of the etrumadenant-based combination, a composite ORR (radiographic and/or PSA [prostate-specific antigen] response) of 41% and a PSA response of 35% were observed. The safety profile was consistent with the known profiles of each individual agent, and no significant additive toxicity was observed with the addition of etrumadenant. These data will be presented in a poster session at the American Society of Clinical Oncology Annual Meeting taking place June 4-8.

"We are encouraged by these early data that indicate the etrumadenant-based combination is well tolerated and demonstrates promising clinical activity in people with advanced disease who progressed on prior treatments," said Bill Grossman, M.D., Ph.D., Chief Medical Officer of Arcus. "Based on these data, we have initiated enrollment into the randomized Phase 2 portion of this arm in the ARC-6 platform study, which compares the etrumadenant-based regimen to standard of care."

"Prostate tumors produce high levels of adenosine, which is believed to be immunosuppressive," said Sumit K. Subudhi, M.D., Ph.D., Department of Genitourinary Medical Oncology, Division of Cancer Medicine at the University of Texas, M.D. Anderson Cancer Center. "I am encouraged by the early evidence of clinical response and composite ORR of 41% observed in this study cohort, indicating adenosine receptor blockade with an etrumadenant-based combination may have a role in the treatment of prostate cancer."

### **ARC-6: A Phase 1b/2, Open-Label, Randomized Platform Study to Evaluate Efficacy and Safety of Etrumadenant (AB928)-Based Treatment Combinations in Patients with Metastatic Castrate-Resistant Prostate Cancer (Abstract 5039)**

As of the data cut-off (DCO) of April 9, 2021, 17 people (n=17) had received the etrumadenant-based combination in this cohort of the Phase 1b portion of the study. Median time on treatment was 4.2 months (range: 2.1-8.3+ months), and 11 people remained on study treatment at time of DCO. For this cohort, all people had received prior systemic therapy but were taxane naive; most (13/17; 76%) had received  $\geq 1$  prior anti-androgen, and 11/17 people (65%) had received prior abiraterone.

#### **Safety Analyses:**

- People in this cohort of the study were administered 150 mg of etrumadenant orally once daily plus 360 mg of zimberelimab and 75mg/m<sup>2</sup> of docetaxel intravenously every three weeks.
- All people experienced treatment emergent adverse events (TEAE), and the most common TEAEs were alopecia (53%), lymphocyte count decreases (53%) and fatigue (47%).
- Grade 3 or 4 related TEAEs were reported for 6/17 (35%) people; all of these events were related to etrumadenant and may also be attributed to zimberelimab and/or docetaxel.
- No treatment emergent serious adverse events (TESAEs) were considered related to etrumadenant.

#### **Clinical Activity:**

- The composite ORR (radiographic and/or PSA response) was 41% (7/17) per the Prostate Cancer Working Group 3 (PCWG3) criteria.
- Six people (35%) had a >50% decrease in PSA level, and seven people (41%) had non-response/non-

progression.

- All 11 people with RECIST measurable or non-measurable disease experienced clinical benefit (stable disease or better).
  - One unconfirmed complete response (CR) was observed in a person with only non-target disease remaining.
  - Two confirmed partial responses (PRs) were observed; one person with PR also had improvement in bone disease burden.

The safety and clinical activity data from this cohort of ARC-6 add to the emerging body of evidence that adenosine receptor blockade with an etrumadenant-based combination may have a role in the treatment of certain cancers. Based on these results, Arcus has initiated the randomized portion of this cohort which is evaluating this etrumadenant-based combination compared to docetaxel, the current standard of care for this setting.

Additional information about this poster presentation may be found on the Arcus website at **Arcus Publications** on June 4.

In addition to ARC-6, etrumadenant is currently being evaluated in three randomized Phase 2 studies:

- ARC-7 is evaluating domvanalimab (anti-TIGIT antibody) plus zimberelimab vs. zimberelimab alone vs. domvanalimab plus zimberelimab and etrumadenant in first-line metastatic, PD-L1 $\geq$ 50%, locally advanced or metastatic non-small cell lung cancer (NSCLC), with an interim analysis planned for this quarter.
- ARC-4 is evaluating etrumadenant plus chemotherapy and zimberelimab vs. chemotherapy plus zimberelimab in second-line (2L) or third-line (3L) EGFR-positive NSCLC. Data from this study are expected in the second half of 2021.
- ARC-9 is evaluating etrumadenant-based combinations in 2L and 3L metastatic colorectal cancer (mCRC). These data build on the results of ARC-3, a Phase 1/1b open-label study of etrumadenant plus chemotherapy in people with mCRC, which showed encouraging tolerability and efficacy in the 3L setting compared to standard of care. Data from this study are expected in the first half of 2022.

## About Etrumadenant

Etrumadenant (AB928), the first dual A2a/A2b adenosine receptor antagonist in the clinic, is designed to maximally inhibit the adenosine-driven impairment of tumor-infiltrating lymphocytes (mainly CD8+ T cells and NK cells) and myeloid cells (dendritic cells, macrophages), mediated by A2aR and A2bR, respectively. A2bR is also upregulated by certain cancer cells, such as in prostate cancer and KRAS-mutated cancers. As a result, etrumadenant may uniquely block adenosine's immunosuppressive and cancer cell-intrinsic effects. Developed specifically for the oncology setting, etrumadenant achieves high penetration of tumor tissue, robust potency in the presence of high adenosine concentrations, and minimal shift in potency from non-specific protein binding. Etrumadenant has demonstrated a

favorable safety profile with a variety of combination regimens and exhibits pharmacokinetics / pharmacodynamics consistent with once-daily oral dosing. AB928 is currently being evaluated in several Phase 1b/2 studies across multiple indications.

## 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 five molecules in clinical development: **Etrumadenant (AB928)**, the first dual A2a/A2b adenosine receptor antagonist to enter the clinic, is being evaluated in multiple Phase 2 and 1b studies across different indications, including prostate, colorectal, non-small cell lung, and pancreatic cancers. **AB680**, the first small-molecule CD73 inhibitor to enter the clinic, is in Phase 1/1b development in combination with zimberelimab and gemcitabine/nab-paclitaxel for first-line treatment of metastatic pancreatic cancer. **Domvanalimab (AB154)**, an anti-TIGIT monoclonal antibody and new potential immuno-oncology backbone therapy, is in a three-arm randomized Phase 2 study evaluating zimberelimab monotherapy, domvanalimab plus zimberelimab and domvanalimab plus etrumadenant plus zimberelimab for first-line treatment of PD-L1  $\geq$  50% metastatic non-small cell lung cancer (NSCLC). In addition, domvanalimab has advanced into ARC-10, Arcus's "two in one trial" to support the potential approvals of both zimberelimab and zimberelimab plus domvanalimab and is expected to advance into a registrational study, in collaboration with AstraZeneca, evaluating the curative-intent stage 3 NSCLC setting later this year. **AB308**, an anti-TIGIT antibody that is FcR-enabled, is in clinical development, with a potential focus on hematological malignancies. **Zimberelimab (AB122)**, Arcus's anti-PD-1 monoclonal antibody, is being evaluated in various combinations across the portfolio. For more information about Arcus Biosciences, please visit [www.arcusbio.com](http://www.arcusbio.com) or follow us on **Twitter**.

## Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the future contained herein, including, but not limited to, the potential role of adenosine receptor blockade in the treatment of certain cancer types, and anticipated milestones and associated timelines 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: the inherent uncertainty associated with pharmaceutical product development and clinical trials; risks associated with preliminary or interim data from ongoing trials; the emergence

of adverse events or other undesirable side effects; the inherent uncertainty associated with the COVID-19 pandemic, including the duration and/or severity of the outbreak and actions by government authorities to contain or slow the spread of the virus; 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; changes in the competitive landscape for our programs; and our dependence on our collaboration with Gilead for the successful development and commercialization of our investigational products. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed on May 5, 2021, 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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