

## Arcus Biosciences Presents Initial Data from the Phase 1 Dose-Escalation Study of AB122, its anti-PD-1 antibody, at the SITC 2018 Annual Meeting

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- Preliminary data demonstrate that AB122 has properties similar to those of approved anti-PD-1 antibodies -

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies, today announced preliminary data from its ongoing Phase 1 dose-escalation study of AB122. The data are being presented today during a poster presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in Washington, D.C.

“Preclinical data previously demonstrated that AB122 has biological, pharmacokinetic and pharmacodynamic properties similar to those of the approved anti-PD-1 antibodies and the dose-escalation data presented today represent an important step in confirming these results in patients,” said Joyson Karakunnel, MD, MSc, FACP, Vice President of Clinical Development at Arcus. “These results support the selection of 240 mg as the AB122 dose for administration every 2 weeks (Q2W); we continue to enroll patients in the Phase 1 study to identify the appropriate doses for administration every 3 weeks (Q3W) or every 4 weeks (Q4W).”

“Since Arcus’s inception, we believed it was important to ensure access to an anti-PD-1 antibody to maximize the value of our internally discovered product candidates, which guided our decision to in-license AB122 from WuXi Biologics, one of the leading biologics manufacturing companies,” said Terry Rosen, Ph.D., Chief Executive Officer at Arcus. “Our development strategy for AB122 is focused on its development in combination with our other product candidates, including AB928, our dual adenosine receptor antagonist, AB680, our small molecule CD73 inhibitor, and AB154, our anti-TIGIT antibody.”

## Design of the Phase 1 Dose-Escalation Study for AB122

The Phase 1 dose-escalation study for AB122 is designed to evaluate the safety, immunogenicity, pharmacokinetic, pharmacodynamic and clinical activity profile of AB122. The Company is evaluating three dosing regimens with the goal of identifying doses of AB122 that can be administered Q2W, Q3W or Q4W.

As of the cutoff date of October 5, 2018, 20 patients had been treated:

- For the Q2W dosing regimen, doses of 80 mg (n=3), 240 mg (n=6), and 360 mg (n=1) were evaluated. 240 mg was identified as the recommended dose for this regimen, based on receptor occupancy data.
- For the Q3W dosing regimen, a dose of 360 mg (n=5) is being evaluated. This cohort continues to enroll patients with the goal of identifying a recommended dose for this regimen.
- For the Q4W dosing regimen, a dose of 480 mg (n=5) is being evaluated. This cohort also continues to enroll patients with the goal of identifying a recommended dose for this regimen.

## Results from the Phase 1 Dose-Escalation Study

As of the data cutoff date:

- The following tumor types were enrolled: ovarian (7), colorectal (3), endometrial (3), gastroesophageal (2), bladder (1), head and neck (1), breast (1), non-small cell lung (1), and prostate (1).
- Time on study ranged from 0.8 to 9.9 months.
- AB122 was well tolerated at all doses evaluated. The majority of treatment emergent adverse events (TEAEs), regardless of causality in all subjects, were Grade 1/2, the most common of which were fatigue (55%) and diarrhea and nausea (25% each). Three patients experienced serious adverse events (SAEs), none of which were considered related to AB122: Grade 2 lower respiratory tract infection, Grade 2 fever and Grade 3 elevated liver function tests secondary to cholelithiasis.
- Data from the three patients in the 80 mg Q2W and six patients in the 240 mg Q2W cohorts showed that AB122 achieved full and sustained receptor occupancy on peripheral blood T cells across all time points in the majority of patients. These data are consistent with published data for approved anti-PD-1 antibodies.
- Of the 16 response-evaluable patients, two patients demonstrated a reduction in tumor size: a patient with head and neck cancer in the 80 mg Q2W cohort and a patient with ovarian cancer in the 360 mg Q2W cohort.
- Disease control rate was 50% in the evaluable patient population. Stable disease was achieved in patients with colorectal cancer (2), ovarian cancer (1) and head and neck cancer (1).

## Ongoing and Planned Clinical Trials for AB122

Arcus is planning to initiate an expansion cohort which will evaluate AB122 in non-small cell lung cancer with the objective of confirming that AB122 has similar clinical activity to that of the approved PD-1 antibodies. AB122 is also being evaluated in combination with AB928, as well as with AB154, in Phase 1/1b dose-escalation trials.

### Details of Arcus's Poster Presentation is as Follows:

**Title:** Preliminary results from an ongoing Phase 1 study of AB122, an anti-programmed cell death-1 (PD-1) monoclonal antibody, in patients with advanced solid tumors.

**Poster Number:** P673; **Abstract ID:** 10638

**Poster Presentation Hours:** Friday, Nov. 9, from 12:45 – 2:15 pm and 6:30 – 8 pm ET

**Poster Hall Location:** Hall E

This poster presentation, as well as the Company's eight other posters being presented at SITC, will be available on Arcus's corporate website at <https://www.arcusbio.com/publications/>.

### **About AB122**

AB122 is a fully human IgG4 antibody that potently and selectively blocks the interaction of PD-1 with its ligands, PD-L1 and PD-L2. The biochemical, biological and preclinical properties of AB122 have been shown to be similar to those of the marketed anti-PD-1 antibodies nivolumab and pembrolizumab. In August 2017, Arcus entered into a license agreement with WuXi Biologics for an exclusive license to develop, use, manufacture, and commercialize AB122 worldwide except for China and five other countries outside of the U.S., Europe and Japan. In November 2017, dosing was initiated in Australia for the Phase 1 trial of AB122 in cancer patients. AB122 is also being evaluated in combination with AB928, the Company's dual adenosine receptor antagonist, in a Phase 1/1b dose-escalation trial. Preliminary data from this trial are expected in the second quarter of 2019. The Company expects AB122 to form the backbone of many of its intra-portfolio combinations.

### **About Arcus Biosciences**

Arcus Biosciences is a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies. Arcus has several programs targeting important immuno-oncology pathways, including a dual adenosine receptor antagonist AB928, which is in a Phase 1/1b program to evaluate AB928 in combination with other agents in multiple tumor types, and an anti-PD-1 antibody AB122, which is being evaluated in a Phase 1 trial and is being tested in combination with Arcus's other product candidates. Arcus's other programs include AB154, an anti-TIGIT antibody, which is in a Phase 1 trial to evaluate AB154 as monotherapy and in combination with

AB122, and AB680, a small molecule inhibitor of CD73, which has entered clinical development. Arcus has extensive in-house expertise in medicinal chemistry, immunology, biochemistry, pharmacology and structural biology. For more information about Arcus Biosciences, please visit [www.arcusbio.com](http://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 strategy and clinical development plans, 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 data and the emergence of adverse events or other undesirable side effects. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended September 30, 2018 filed on November 8, 2018 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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