

# Arcus Biosciences Announces FDA Clearance of INDs for AB928 and AB122 and Initiation of Phase 1/1b Program to Evaluate AB928 Combinations

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HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has cleared Investigational New Drug (IND) applications for the Company's two most advanced product candidates, AB928 and AB122. Clearance of the first IND for AB928 allows the Company to proceed with its planned Phase 1/1b trial to evaluate the safety, tolerability and preliminary efficacy of AB928 in combination with other agents, including AB122 (the Company's anti-PD-1 antibody) and chemotherapy, in patients with breast and gynecologic malignancies. Two additional IND applications will be submitted this month which, if cleared, will enable the Company to proceed with trials of AB928 combinations in gastrointestinal malignancies, non-small cell lung cancer (NSCLC) and renal cell carcinoma (RCC). In parallel, the Company has been completing the regulatory process to evaluate the combination of AB928 and AB122 in patients in Australia and expects to dose its first patient with this combination shortly.

"We are thrilled to receive our first IND clearances to permit dosing in patients for AB928, our dual adenosine receptor antagonist, in combination with other anti-cancer agents," said Terry Rosen, Ph.D., Chief Executive Officer at Arcus. "For our initial Phase 1/1b combination trials for AB928, we have selected tumor types that we believe will be most responsive to adenosine 2 receptor antagonism and combination partners that we expect to be synergistic with this mechanism, specifically immunogenic cell death (ICD) inducing chemotherapy and anti-PD-1 therapy. We have designed our Phase 1/1b program for AB928 to provide us with significant flexibility to open new arms to evaluate promising combinations and to expand or close existing arms based on the emerging data. We are extremely pleased to begin testing in patients the first adenosine 2 receptor antagonist that was specifically

designed to be a therapeutic for cancer.”

The Phase 1/1b program for AB928 will initially evaluate AB928 in combination with AB122 and with chemotherapy in three tumor-specific trials. The Phase 1/1b program will begin with a dose-escalation phase to identify the optimal dose of AB928 to be combined with fixed doses of AB122 and with each of the three different ICD-inducing chemotherapy regimens. Once the recommended dose of AB928 for each combination has been selected, the tumor-specific trials will enroll expansion cohorts to evaluate AB928 in combination with AB122 or chemotherapy in the following selected tumor types:

- **Breast and Gynecologic Malignancies.** This trial will initially evaluate AB928 in combination with AB122 and with DOXIL® in triple negative breast cancer and ovarian cancer. The FDA has cleared the IND application for this trial.
- **Gastrointestinal Malignancies.** This trial will initially evaluate AB928 in combination with AB122 and with mFOLFOX in gastroesophageal and colorectal cancers. The IND application for this trial will be submitted this month.
- **Lung Cancer and Renal Cell Carcinoma.** This trial will initially evaluate AB928 in combination with AB122 in NSCLC and RCC as well as AB928 in combination with a platinum-based chemotherapy regimen in NSCLC. The trial design will also allow for the exploration of additional AB928 combinations, including triple combinations, and AB928 in combination with other anti-PD-1 antibodies. The IND application for this trial will be submitted this month.

Each trial was designed to allow for the addition of new AB928 combination arms in the future. In the dose-escalation portion of the trials, the Company will assess evidence of immune engagement to enable a mechanistic understanding of early clinical responses and will evaluate the suitability of several potential biomarkers for patient enrichment in the dose-expansion cohorts and in future trials.

Data from the dose-escalation portion of the Phase 1/1b program are expected to be available in the first half of 2019.

## About AB928

AB928 is an orally bioavailable, highly potent antagonist of the adenosine 2a and 2b receptors. The activation of these receptors by adenosine interferes with the activity of key populations of immune cells and inhibits an optimal anti-tumor immune response. By blocking these receptors, AB928 has the potential to reverse adenosine-induced immune suppression within the tumor microenvironment. AB928 was designed specifically for the oncology setting, with a profile that includes potent activity in the presence of high concentrations of adenosine and a minimal shift

in potency due to non-specific protein binding, both essential properties to be efficacious in the tumor microenvironment. AB928 has other attractive features, including high penetration of tumor tissue and low penetration through the healthy blood-brain barrier. In a Phase 1 trial in healthy volunteers, AB928 has been shown to be safe and well tolerated and to have pharmacokinetic and pharmacodynamic profiles consistent with a once-daily dosing regimen.

## 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 will be evaluated in combination with other agents in multiple tumor types in a Phase 1/1b program, and an anti-PD-1 antibody, which is being evaluated in a Phase 1 trial and will be tested in combination with Arcus's other product candidates. Arcus's other programs include a small molecule inhibitor of CD73 and an anti-TIGIT antibody, both of which are in IND-enabling studies. 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 regulatory submission timelines, clinical development plans and investigations of biomarkers and immune engagement, 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, 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 that the results of biomarker analyses and immune engagement may be subject to differing interpretations. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended March 31, 2018 filed on May 9, 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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Arcus Biosciences, Inc.

Jennifer Jarrett, 510-694-6261

**[jjarrett@arcusbio.com](mailto:jjarrett@arcusbio.com)**

or

Nicole Arndt, 510-284-4728

**[narndt@arcusbio.com](mailto:narndt@arcusbio.com)**

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