

Arcus Biosciences Presents Phase 1 Data for AB928 in Healthy Volunteers at 2018 AACR Annual Meeting

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HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies, will present data today from its Phase 1 trial for AB928, its dual adenosine receptor antagonist, in healthy volunteers in a poster presentation titled "Clinical Pharmacokinetic-Pharmacodynamic Relationship for AB928, a Dual Antagonist of the A2aR and A2bR Adenosine Receptors," at the 2018 American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois.

"We are extremely encouraged by the results from our ongoing Phase 1 trial of AB928. The compound has been shown to be safe and well tolerated at all doses evaluated and achieves near complete inhibition of A2aR adenosine receptor activation in blood samples from healthy volunteers," said Terry Rosen, Ph.D., Chief Executive Officer at Arcus. "Importantly, we achieved this level of inhibition under conditions that we believe are representative of the large concentrations of adenosine found in the tumor microenvironment. These results have informed the selection of the starting dose for our clinical trials of AB928 in combination with other anti-cancer agents, and we look forward to starting these trials shortly."

Design of the Phase 1 Trial for AB928 in Healthy Volunteers

The Phase 1 double-blinded, placebo-controlled trial has enrolled 85 healthy volunteers. The trial includes a single-ascending-dose (SAD) portion as well as a multiple-ascending-dose (MAD) portion. In the SAD portion, single doses of 10, 25, 75 and 150 mg and a twice-daily dose of 100 mg have been evaluated. In the MAD portion, doses of 10, 25, 75 and 150 mg QD and 200 mg QD (with food) have been administered to subjects for four consecutive days. In each dosing cohort, 6 subjects received AB928 and 2 subjects received placebo, and dosing in the trial has been completed. Investigators remain blinded regarding subject assignment to the AB928 or placebo arms.

The objective of this trial is to assess the safety, tolerability, pharmacokinetics and pharmacodynamic profile of AB928 and to inform our selection of the starting dose of AB928 for our combination trials in cancer patients.

Summary of the Results Presented

All doses have been safe and well tolerated, and no safety events prevented escalation to higher doses. To assess the pharmacodynamic effects of AB928, blood samples were taken from subjects at different time points following the administration of AB928 or placebo. As of the cut-off date (COD) of March 30, 2018 for the poster presentation, samples from all dosing cohorts, with the exception of the 200 mg QD (with food) MAD cohort, have been evaluated to assess the pharmacodynamic effects of AB928. These samples were treated with NECA (a synthetic analogue of adenosine), which activates A2aR receptors on T cells. The ability of AB928 to block A2aR receptors on T cells was quantified by measuring the levels of pCREB, which is a marker for activation of the A2aR receptor.

When blood samples from the 150 mg MAD cohort were incubated with 5 μ M NECA, AB928 achieved complete inhibition of pCREB activation at two hours post-dosing and approximately 90% mean inhibition of pCREB activation at 24 hours post-dosing on day 4. As experiments conducted in vitro by Arcus have demonstrated that NECA is at least 20 times more potent than adenosine at inducing pCREB activation in blood T cells, stimulation with 5 μ M NECA should be comparable to stimulation with adenosine concentrations in excess of 100 μ M.

The pharmacokinetic profile of AB928 supports once-daily dosing, with a plasma half-life that exceeds 20 hours.

Complete results from this trial, including pharmacodynamic data for the 200 mg BID (with food) dosing cohort, will be released following the unblinding of data in mid-2018.

AB928 Clinical Development Plans

The results from this healthy volunteer trial demonstrate that a safe and well tolerated dose of AB928 can provide near complete inhibition of A2aR receptor activation. Based on these results, Arcus is preparing to initiate clinical trials to evaluate AB928 in combination with three different chemotherapy regimens and in combination with AB122, its PD-1 antibody, in cancer patients. Regulatory submissions to start these trials are underway.

These trials will include a dose-escalation portion to identify the recommended dose of AB928 for each combination regimen. Based on the safety profile of AB928, the initial dose of AB928 for the dose-escalation portion should achieve close to complete inhibition of A2aR receptor activation. Once the recommended dose has been selected, AB928 will be evaluated in 11 expansion cohorts. Each expansion cohort will evaluate the AB928 + chemotherapy combination and/or the AB928 + AB122 combination in one of the following tumor types: non-small

cell lung cancer, renal cell carcinoma, gastroesophageal cancer, colorectal cancer, ovarian cancer and triple negative breast cancer. In both the dose escalation portion and expansion cohorts, Arcus will conduct significant biomarker analysis, which will inform patient selection in future trials. Arcus plans to report data from the dose-escalation portion of these trials in the first half of 2019.

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 and an anti-PD-1 antibody, both of which are in Phase 1 trials, as well as a small molecule inhibitor of CD73 and an anti-TIGIT antibody, 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.

Forward-Looking Statement

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including, but not limited to, Arcus's 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; the applicability of the results described herein to Arcus's clinical development plans and subsequent clinical trials; risks associated with preliminary data; and 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. Risks and uncertainties facing Arcus are described more fully in Arcus's registration statement on Form S-1 as filed 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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