

Arcus Biosciences Announces Final Safety Results From Phase 1 Trial for AB928 in Healthy Volunteers

7/17/2018

- AB928 was safe and well tolerated at all doses evaluated -

- Safety and pharmacodynamic data from healthy volunteer trial support selection of dose for evaluation of AB928 in combination with anti-PD-1 therapy in patients -

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies, today announced the final unblinded safety data from its Phase 1 trial for AB928, its dual adenosine receptor antagonist, in healthy volunteers. These results demonstrated that AB928 was safe and well tolerated at all doses evaluated. Pharmacokinetic and pharmacodynamic data from this trial were previously presented in April at the 2018 American Association for Cancer Research (AACR) Annual Meeting.

“We are pleased to see that AB928 was safe and well tolerated in healthy volunteers, even at 200 mg once-daily, the highest dose tested in the study. In addition, pharmacodynamic data from this trial demonstrated that an AB928 dose between 75 mg and 150 mg once-daily should be sufficient to achieve greater than 90% inhibition of the adenosine 2a (A2a) receptor pathway,” said Joyson Karakunnel, MD, MSc, FACP, Vice President of Clinical Development at Arcus. “These results demonstrate that AB928 has an attractive profile to be combined with standard-of-care regimens for the treatment of cancer, such as anti-PD-1 antibodies or chemotherapy, particularly in settings where adenosine is believed to play an immuno-suppressive role. The results also support the selection of the starting dose for the combination of AB928 and AB122, our anti-PD-1 antibody, in patients.”

Design of the Phase 1 Trial for AB928 in Healthy Volunteers

The Phase 1 double-blinded, randomized, placebo-controlled trial enrolled 85 healthy volunteers. The trial included a single-ascending-dose (SAD) portion and 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 were evaluated. In the MAD portion, once-daily doses of 10, 25, 75 and 150 mg and 200 mg (with food) were administered to subjects for four consecutive days. In each dosing cohort, six subjects received AB928 and two subjects received placebo.

Summary of the Phase 1 Safety Results

- All reported adverse events (AEs) were characterized as low-grade AEs (Grade 1 or Grade 2), with the majority of the AEs being Grade 1 events.
- No AEs appeared to be dose dependent, and no AEs prevented escalation to a higher dose.
- All treatment-related AEs were resolved by the end of the study period, and no serious adverse events, discontinuations or deaths were reported in the study.
- There were no variations in heart rate or blood pressure that would not be considered within normal parameters.

Based on the results from the healthy-volunteer trial, patients in the first dose-escalation cohort for the Phase 1/1b program, which will evaluate AB928 + AB122, will receive once-daily doses of 75 mg of AB928. The Company plans to present the final safety results from the Phase 1 healthy-volunteer trial at a medical conference later in the year.

About the Phase 1/1b Program for AB928

The Phase 1/1b program for AB928 is designed to evaluate the safety and clinical activity of the combinations of AB928 + AB122 and AB928 + chemotherapy in selected tumor types characterized by high levels of adenosine and / or CD73 as well as T cell infiltration. These tumor types include triple negative breast cancer, ovarian cancer, colorectal cancer, gastroesophageal cancer, non-small cell lung cancer and renal cell carcinoma. As part of the Phase 1/1b program, the Company also expects to evaluate the triple combination of AB928 + anti-PD-1 therapy + chemotherapy in certain settings such as non-small cell lung cancer. The Company plans to present dose-escalation data for the combinations, including data on safety, biomarker analysis and clinical activity, 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 for efficacy 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 AB122

AB122 is a fully human IgG4 antibody that potently and selectively blocks PD-1. 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, Japan. In November 2017, dosing was initiated in Australia for the Phase 1 trial of AB122 in cancer patients. The Company plans to report initial data from this trial in the third quarter of 2018. 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 will be evaluated in combination with other agents in multiple tumor types in a Phase 1/1b program, and an anti-PD-1 antibody AB122, 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.

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, the attractiveness of AB928's profile, its use in combination with other anti-cancer agents and timelines for Arcus's clinical programs, 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 emergence of drug-related adverse events in combination trials of AB928 and other anti-cancer agents, delays in the company's 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 clinical trials 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.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20180717005306/en/>

Arcus Biosciences

Jennifer Jarrett, 510-694-6261

jjarrett@arcusbio.com

or

Nicole Arndt, 510-284-4728

narndt@arcusbio.com

Source: Arcus Biosciences