NEWS RELEASE

Data from a Phase 1b Study of Quemliclustat-Based Regimens Showed Promising Overall Survival in Treatment-Naïve Metastatic Pancreatic Cancer

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- Median Overall Survival was 15.7 months for all patients treated with 100 mg quemliclustat-based regimens in the ARC-8 study, which exceeds the historical benchmark data for chemotherapy alone
- A 37% reduction in risk of death and a 5.9-month improvement in median overall survival was observed for patients treated with quemliclustat-based regimens when compared to a Synthetic Control Arm® (SCA®) of patients treated with chemotherapy alone in a post-hoc analysis
- Detailed results will be presented at the ASCO Gastrointestinal Cancers Symposium on January 19 from 12:30 – 2:00pm PT / 3:30 – 5:00pm ET

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS) today announced promising overall survival data from ARC-8, a Phase 1b study that is being co-developed with Gilead Sciences. ARC-8 is the study of quemliclustat, an investigational small molecule CD73 inhibitor, plus chemotherapy with or without zimberelimab, an investigational anti-PD-1 antibody, in patients with previously untreated metastatic pancreatic ductal adenocarcinoma (mPDAC). The results will be presented during the 2024 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI).

“A quemliclustat-based regimen appears to meaningfully prolong survival compared to what we typically observe in patients with mPDAC who receive chemotherapy alone, the standard of care for more than 30 years,” said Zev A.

Wainberg, MD, MSc, Co-Director of the GI Oncology Program at University of California Los Angeles and a principal investigator of the ARC-8 trial. “CD73 is highly expressed on pancreatic cancer cells, and I am encouraged to see early evidence that inhibiting CD73 with a small molecule has the potential to improve outcomes for people with mPDAC, without an observed clinically meaningful increase in toxicity, when combined with standard of care chemotherapy relative to historical data for chemotherapy alone.”

The results to be presented include data from all patients (n=122) with treatment-naïve (first-line) mPDAC who received 100mg of quemliclustat plus chemotherapy with or without zimberelimab in the dose-escalation, dose-expansion and randomization cohorts of ARC-8. The data cutoff was June 19, 2023. Median overall survival (mOS) data for both quemliclustat-based regimens were numerically greater than historical benchmark data for chemotherapy alone, which has shown a mOS of approximately nine months.

An analysis was performed by the Medidata AI team, part of Medidata, a Dassault Systèmes company, whereby they constructed a Synthetic Control Arm of patients who were treated with gemcitabine/nab-paclitaxel in Phase 2 and 3 clinical studies in the first-line metastatic pancreatic cancer setting, on a post-hoc basis. Patients from these studies were matched 1:1 to the pool of 122 patients treated with the 100 mg quemliclustat-based regimens in ARC-8, based on demographics and key baseline characteristics such as ECOG performance status, liver metastasis, and history of prior surgery. The matched SCA was constructed based on a pre-specified analysis plan before OS data were unblinded and analyzed by the Medidata AI team. The analysis showed that the patients in ARC-8 lived longer than patients from the matched control arm. Specifically, these results showed that patients in ARC-8 experienced a:

- 37% reduction in the risk of death, HR=0.63 (CI: 0.47 – 0.85, p=0.0030) and a
- 5.9-month increase in mOS (15.7 vs 9.8 months) relative to the matched control arm.

The efficacy data for the pooled dose-escalation, dose-expansion and randomized arms, as well as the data from the SCA, are summarized below:

	A2: Q+G/nP* (n=29)	A1: QZ+G/nP** (n=61)	Pooled Q100 QZ+G/nP*** (n=93)	All Pooled Q100 Q±Z+G/nP (n=122)****	Post-hoc Synthetic Control Arm (n=122)*****
Median OS, months (95% CI)	19.4 (12.1, 23.0)	14.6 (10.6, 21.5)	13.9 (11.1, 18.7)	15.7 (12.4, 20.9)	9.8 (7.8, 11.4)
Hazard Ratio (95% CI)				HR=0.63 (0.47 – 0.85) p=0.0030)	
12-month OS	72.3%	60.9%	59.6%	62.7%	41.1%
Median PFS, months (95% CI)	8.8 (6.4, 12.6)	4.9 (3.7, 6.0)	5.4 (4.9, 7.3)	6.3 (5.4, 7.7)	5.5 (4.4, 6.6)
Hazard Ratio				HR=0.78 (0.58-1.05) p=0.1102	

(95% CI)				p=0.1102	
ORR, % (95% CI)	41 (24, 61)	34 (23, 48)	38 (28, 48)	39 (29.9, 47.8)	41 (32.2, 50.3)

Q, Quemliclustat; Z, Zimberelimab; G/nP, gemcitabine / nab-paclitaxel; CI, confidence interval
*Cohort A2 – patients randomized to Q+G/nP in the dose-expansion phase.
**Cohort A1 – patients randomized to QZ+G/nP in the dose-expansion phase.
***Pooled Q100 QZ+G/nP – treatment-naïve patients receiving 100 mg of quemliclustat plus zimberelimab and G/nP across dose- escalation, expansion and randomization phases.
****All Pooled – treatment-naïve patients receiving 100 mg of quemliclustat with or without zimberelimab across dose- escalation, dose-expansion and randomization phases.
*****Synthetic Control Arm (Historical Control) – Historical clinical trial data from patients treated with G/nP, balanced to the baseline characteristics of ARC-8 participants. The Synthetic Control Arm data were compared to the All Pooled group.

No new safety signals were observed in the study. The most common adverse events (Grade 3 or higher) were neutropenia (37.9%, 34.4% and 38.7%) and anemia (27.6%, 26.2% and 23.7%), respectively, for cohorts A2, A1 and Pooled Q100 QZ+G/nP. Five deaths were reported, and none were considered by the study investigators to be related to quemliclustat or zimberelimab.

Quemliclustat and zimberelimab are investigational molecules. Arcus and Gilead have not received approval from any regulatory authority for any use globally, and their safety and efficacy for the treatment of pancreatic cancer have not been established.

About Quemliclustat

Quemliclustat is an investigational, potent and selective small molecule CD73 inhibitor. CD73 is the primary enzymatic producer of immunosuppressive adenosine in the tumor microenvironment, and high CD73 expression is associated with significantly poorer prognosis in several tumor types. Quemliclustat has been shown to block the production of adenosine. Once the immunosuppressive effects of adenosine are removed, activation of antitumor immune cells may be restored, resulting in cancer cell death.

Arcus and Gilead are currently evaluating quemliclustat in combination with other molecules within the collaboration portfolio with chemotherapy, including Phase 2 studies in lung and upper gastrointestinal cancers.

About the ARC-8 Trial

The ARC-8 trial is a Phase 1b, open-label, dose-escalation and dose-expansion platform study to evaluate the safety, tolerability, pharmacokinetic, pharmacodynamic and clinical activity of combinations of the small molecule CD73

inhibitor quemliclustat, anti-PD-1 antibody zimberelimab and chemotherapy (gemcitabine / nab-paclitaxel, or G/nP) in participants with advanced pancreatic cancer.

After the dose-escalation phase, quemliclustat 100 mg was selected as the dose for expansion. Patients were treated with quemliclustat 100 mg every two weeks plus standard doses of chemotherapy and zimberelimab (240 mg IV every two weeks) in Cohort A (treatment-naïve mPDAC) of the dose-expansion phase and then randomized 2:1 to receive quemliclustat plus zimberelimab and chemotherapy (Cohort A1) or quemliclustat plus chemotherapy (Cohort A2). Pooled analyses were conducted to reflect: 1) all treatment-naïve patients who received quemliclustat 100 mg plus zimberelimab and chemotherapy from dose-escalation and dose-expansion phases and 2) all treatment-naïve patients receiving 100 mg of quemliclustat with or without zimberelimab across dose-expansion and escalation phases. Endpoints included safety, overall response rate, median overall survival and progression-free survival. More information about ARC-8 is available at: **https://www.clinicaltrials.gov/study/NCT04104672**.

Additionally, an analysis comparing the All Pooled cohort to a Synthetic Control Arm (SCA) was conducted to address the differences in patient characteristics in the study cohorts, particularly in relation to decreased presence of liver metastases at baseline in cohort A2. The SCA consisted of historical clinical trial data from patients treated with G/nP, with baseline characteristics matched to those of ARC-8 participants.

About Pancreatic Cancer

Pancreatic cancer occurs in the pancreas, an organ located behind the stomach that helps with digestion and controlling blood sugar. Pancreatic cancer is one of the most aggressive cancers, with a dismal prognosis. Approximately 50% of patients with PDAC are diagnosed in the metastatic setting, which is associated with a 5-year survival rate of only 3%. Over 80% of pancreatic cancers are diagnosed at a late stage. The majority (over 90%) of pancreatic cancers are adenocarcinomas, a type of cancer that forms in tissues that line certain internal organs and release fluids like those that help with digestion. There have been limited advancements for treating pancreatic cancer, and chemotherapy has been the standard of care for more than 30 years.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company developing differentiated molecules and combination medicines for people with cancer. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of first- and best-in-class medicines against well-characterized biological targets and pathways and studying novel, biology-driven combinations that have the potential to help people with cancer live longer. Founded in 2015, the company has expedited the development of multiple investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-

1, the adenosine axis (CD73 and dual A2a/A2b receptor), HIF-2a, CD39 and AXL. For more information about Arcus Biosciences' clinical and pre-clinical programs, please visit **www.arcusbio.com**.

Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the future contained herein 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, including, but not limited to, the statements in Dr. Wainberg's quote and statements regarding: the timing and scope of analyses, data disclosures and presentations; whether data and results from current studies support further development of a program; and the potency, efficacy or safety of Arcus's investigational products. All forward-looking statements involve known and unknown risks and uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: risks associated with preliminary and interim data not being guarantees that future data will be similar; the unexpected emergence of adverse events or other undesirable side effects; difficulties or delays in initiating or conducting clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; Arcus's dependence on the collaboration with Gilead for the successful development and commercialization of its optioned molecules; difficulties associated with the management of the collaboration activities or expanded clinical programs; changes in the competitive landscape for Arcus's programs; and the inherent uncertainty associated with pharmaceutical product development and clinical trials. Risks and uncertainties facing Arcus are described more fully in the "Risk Factors" section of Arcus's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission. 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 except to the extent required by law.

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