NEWS RELEASE

Arcus Biosciences Reports Fourth-Quarter and Full-Year 2023 Financial Results and Provides a Pipeline Update

2/21/2024

- Arcus and Gilead announced an additional equity investment of $320 million into Arcus and modifications to their domvanalimab + zimberelimab clinical program to focus on the highest unmet medical needs and largest market opportunities

- Pharmacokinetic (PK), pharmacodynamic (PD), safety and early efficacy data, including initial observations from the expansion cohort, from ARC-20, support potential for casdatifan (AB521) to result in greater HIF-2a inhibition than the marketed competitor; expansion cohort data expected to be presented in the second half of 2024

- Multiple datasets expected to be presented in the first half of 2024 including EDGE-Gastric for domvanalimab + zimberelimab + chemotherapy at ASCO and two randomized datasets for etrumadenant

- $1.2 billion in pro forma cash, cash equivalents and marketable securities and funding into 2027 to support Phase 3 trials for 3 different molecules and launch preparations

- Conference call today at 2:00 PM PT / 5:00 PM ET

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical

company focused on developing differentiated molecules and combination therapies for people with cancer, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a pipeline update on its clinical-stage investigational molecules – targeting TIGIT, the adenosine axis (CD73 and A2a/A2b receptors), HIF-2a, AXL and PD-1 – across multiple common cancers.

"By the beginning of next year, we expect to have six ongoing Phase 3 trials for three distinct programs: domvanalimab plus zimberelimab, our Fc-silent anti-TIGIT antibody and anti-PD-1 antibody combination; casdatifan (AB521), our HIF-2a inhibitor; and quemliclustat, our CD73 inhibitor. Two of our Phase 3 trials (STAR-121 and STAR-221) for domvanalimab plus zimberelimab are expected to complete enrollment this year, and we are beginning preparations for regulatory filings," said Terry Rosen, Ph.D., chief executive officer of Arcus. "We now have cash runway into 2027, enabling us to accelerate our multiple late-clinical stage studies and support our highly productive discovery engine."

Corporate Update:

- In January 2024, Gilead and Arcus announced an amendment to their collaboration agreement and a separate equity investment, raising Gilead's ownership stake to 33%. In connection with the announcement, Gilead's Chief Commercial Officer, Johanna Mercier, joined Arcus's board.
- In December 2023, Arcus and Exelixis announced a clinical trial collaboration for STELLAR-009, a Phase 1b/2 trial evaluating casdatifan in combination with zanzalintinib in patients with advanced solid tumors, including clear cell renal cell carcinoma (ccRCC). The trial is currently enrolling.

Pipeline Highlights:

Domvanalimab (Fc-silent anti-TIGIT monoclonal antibody) plus Zimberelimab (anti-PD-1 antibody)

Domvanalimab-zimberelimab Updates:

- Arcus and Gilead announced strategic changes and enrollment updates to their domvanalimab + zimberelimab clinical program to focus on settings with the highest unmet medical need and where the Fc-silent design of domvanalimab has the potential for differentiation in both efficacy and safety.
    - Enrollment was discontinued for the Phase 3 study ARC-10 evaluating domvanalimab plus zimberelimab compared to pembrolizumab in first-line PD-L1-high NSCLC. This enables a potential acceleration of the Phase 3 study STAR-121 in the all-comer first-line NSCLC setting.
    - Arcus and Gilead plan to initiate STAR-131, a registrational Phase 3 study in perioperative NSCLC.
    - The companies also plan to initiate a Phase 2 trial to evaluate domvanalimab plus zimberelimab in a

new disease setting.

Upcoming Domvanalimab-Zimberelimab Milestones:

- Updated PFS and ORR data from the Phase 2 EDGE-Gastric trial evaluating domvanalimab + zimberelimab + chemotherapy in first-line upper GI cancers are expected to be presented at the ASCO Annual Meeting in June 2024. This study is evaluating a similar regimen and patient population as our STAR-221 phase 3 study.
- Data and insights from previously enrolled patients in the ARC-10 study (Part 1) are expected to be shared at future scientific conferences.
- The Phase 3 studies STAR-221 and STAR-121 are expected to complete enrollment by year-end.

Casdatifan, also known as AB521 (HIF-2a inhibitor)

Casdatifan (AB521) Updates:

- Arcus shared PK, PD, safety, and early efficacy data from the dose-escalation phase of ARC-20, a Phase 1/1b study of casdatifan in cancer patients.
    - PK, PD, and Safety Data:
        - PD data demonstrated that a 20 mg daily dose of casdatifan (one-fifth the selected Phase 3 dose of 100 mg) achieved a similar level of HIF-2a-mediated EPO suppression as the 120 mg approved dose of the marketed competitor, belzutifan.
        - Dose-proportional PK were observed through the selected Phase 3 dose of 100 mg of casdatifan. By contrast, plasma levels of belzutifan do not meaningfully increase above the approved dose of 120 mg.
        - Together, the PK and PD profile observed suggests that the selected dose of 100mg of casdatifan has the potential to achieve substantially greater HIF-2a inhibition than the approved dose of belzutifan.
        - No dose-limiting toxicities have been observed to date in ARC-20.
        - To date, rates of adverse events, including anemia and hypoxia, appear consistent with observations from historical trials of belzutifan.
    - Early efficacy data from the dose-escalation and 100 mg dose-expansion cohorts will be discussed on today's conference call.
- Arcus intends to initiate a Phase 3 combination study in ccRCC in early 2025.

Upcoming Casdatifan (AB521) Milestones:

- Efficacy data from the dose-expansion stage of the ARC-20 study are expected to be presented at a medical

conference in the second half of 2024.

- The data will focus on the cohort of 30 patients treated with a 100 mg daily dose of casdatifan.
- In addition, a 50 mg daily expansion cohort is currently enrolling and a to-be-determined higher dose expansion cohort is planned; data from these cohorts will be shared at a later date.

Quemliclustat (small-molecule CD73 inhibitor)

- Arcus presented overall survival data at the 2024 ASCO GI conference from the ongoing Phase 1/1b ARC-8 trial evaluating quemliclustat plus chemotherapy with or without zimberelimab in patients with previously untreated metastatic pancreatic ductal adenocarcinoma (mPDAC).
  - Median Overall Survival (mOS) was 15.7 months for all patients treated with 100 mg quemliclustat-based regimens (pooled analysis) 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 mOS was observed for patients treated with quemliclustat-based regimens when compared to a Synthetic Control Arm of 1:1 matched patients who were treated with gemcitabine/nab-paclitaxel in Phase 2 and 3 clinical studies in a post hoc analysis.
- Initiation of a Phase 3 trial in pancreatic cancer is expected to begin by early 2025.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

- Data from ARC-9, a randomized Phase 1b/2 study evaluating etrumadenant plus zimberelimab plus chemotherapy versus regorafenib in third-line metastatic colorectal cancer (mCRC) are expected to be presented in the first half of 2024.
- Data from MORPHEUS-PDAC, a randomized Phase 2 platform study operationalized by Roche evaluating etrumadenant plus atezolizumab plus chemotherapy versus chemotherapy in first-line metastatic pancreatic ductal adenocarcinoma, are expected to be presented in the first half of 2024.

Early Clinical and Preclinical Programs

- Arcus initiated ARC-27, a Phase 1 study of AB801, Arcus's potent and highly selective AXL inhibitor, in advanced cancer patients and expects to initiate the first expansion cohort in NSCLC in 2025.
- Arcus is conducting preclinical toxicity studies on multiple development candidates against KIT, a target involved in multiple allergic and immune-mediated diseases.

Financial Results for Fourth Quarter and Full Year 2023:

- Cash, Cash Equivalents and Marketable Securities were $866 million as of December 31, 2023, compared to

$1.1 billion as of December 31, 2022. The decrease during the year is primarily due to the use of cash in research and development activities, partially offset by receipts totaling $49 million in upfront and milestone payments from Gilead and Taiho, and $33 million in proceeds from the issuance of 2.6 million shares of our common stock including shares pursuant to an equity award plan. Together with the $320 million we received from Gilead for their equity investment in January 2024, our cash, cash equivalents and marketable securities were $1.2 billion, which we believe will be sufficient to fund our planned operations into 2027. Cash, cash equivalents and marketable securities are expected to be between $870 and $920 million at the end of 2024.

- Revenues were $31 million for the fourth quarter 2023, compared to $34 million for the same period in 2022. In the fourth quarter 2023, Arcus recognized $22 million in License and development service revenues related to the advancement of programs, primarily the Gilead collaboration, as well as $9 million in Other collaboration revenue primarily related to Gilead's ongoing rights to access Arcus's research and development pipeline in accordance with the Gilead collaboration agreement. Revenues were $117 million for the full year 2023, compared to $112 million for the same period in 2022.
- Research and Development (R&D) Expenses were $93 million for the fourth quarter 2023, compared to $80 million for the same period in 2022. The net increase of $13 million was primarily driven by higher costs to support our late-stage development program activities. Non-cash stock-based compensation expense was $9 million for each of the fourth quarter 2023 and 2022. R&D expenses were $340 million for the full year 2023, compared to $288 million for the same period in 2022. For fourth quarter 2023 and 2022, Arcus recognized gross reimbursements of $42 million and $49 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration. Gross reimbursements were $162 million for the full year 2023, compared to $161 million for 2022. R&D expense by quarter may fluctuate due to the timing of clinical manufacturing and standard-of-care therapeutic purchases with a corresponding impact on reimbursements.
- General and Administrative (G&A) Expenses were $29 million for the fourth quarter 2023, compared to $28 million for the same period in 2022. Non-cash stock-based compensation expense was $9 million for the fourth quarter 2023, compared to $8 million for the same period in 2022. G&A expenses were $117 million for the full year 2023, compared to $104 million for 2022.
- Net Loss was $81 million for the fourth quarter 2023, compared to $67 million for the same period in 2022. The increase in net loss included an increase of $1 million in income tax expense primarily due to an increase in taxable income compared to the prior year. Net loss was $307 million for the full year 2023, compared to $267 million for 2022.

Conference Call Information:

Arcus will host a conference call and webcast today, February 21, at 2:00 PM PT / 5:00 PM ET to discuss its fourth-quarter and full-year 2023 financial results and pipeline updates. To access the call, please dial (404) 975-4839 (local) or (833) 470-1428 (toll-free), using Access Code: 235272. To access the live webcast and accompanying slide presentation, please visit the "Investors & Media" section of the Arcus Biosciences website at **www.arcusbio.com**. A

replay of the webcast will be available following the live event.

Arcus Ongoing and Announced Clinical Studies:

Trial Name	Arms	Setting	Status	NCT No.
Lung Cancer				
PACIFIC-8	dom + durva vs. durva	Unresectable Stage 3 NSCLC	Ongoing Registrational Phase 3	NCT05211895
STAR-121	dom + zim + chemo vs. pembro + chemo	1L NSCLC (PD-L1 all-comers)	Ongoing Registrational Phase 3	NCT05502237
STAR-131	dom + zim + chemo; dom + zim	Perioperative NSCLC	Planned Registrational Phase 3	TBD
EDGE-Lung	dom +/- zim +/- quemli +/- chemo	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	NCT05676931
VELOCITY-Lung	dom +/- zim +/- etruma +/- sacituzumab govitecan-hziy or other combos	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	NCT05633667
Gastrointestinal Cancers				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	NCT04660812
EDGE-Gastric (ARC-21)	dom +/- zim +/- quemli +/- chemo	1L/2L Upper GI Malignancies	Ongoing Randomized Phase 2	NCT05329766
STAR-221	dom + zim + chemo vs. nivo + chemo	1L Gastric, Gastroesophageal Junction (GEJ) and Esophageal Adenocarcinoma (EAC)	Ongoing Registrational Phase 3	NCT05568095
Pancreatic Cancer				
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L, 2L PDAC	Ongoing Randomized Phase 1/1b	NCT04104672
Prostate Cancer				
ARC-6	etruma + zim + SOC vs. SOC	2L/3L CRPC	Ongoing Randomized Phase 2	NCT04381832
Kidney Cancer				
ARC-20	cas	Cancer Patients / ccRCC	Ongoing Phase 1/1b	NCT05536141
STELLAR-009	cas + zanza	ccRCC	Ongoing Phase 1b/2	NCT06191796
Other				
ARC-25	AB598	Advanced Malignancies	Ongoing	NCT05891171
ARC-26	AB801	Healthy Volunteers	Ongoing	NCT06004921
ARC-27	AB801	Advanced Malignancies	Ongoing	NCT06120075

cas: casdatifan; dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; nivo: nivolumab; pembro: pembrolizumab; quemli: quemliclustat; SOC: standard of care; zanza: zanzalintinib; zim: zimberelimab; ccRCC: clear-cell renal cell carcinoma; CRC: colorectal cancer; CRPC: castrate-resistant prostate cancer; GI: gastrointestinal; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma

About the Gilead Collaboration

In May 2020, Arcus established a 10-year collaboration with Gilead to strategically advance our portfolio. Under this collaboration, Gilead obtained time-limited exclusive option rights to all of our clinical programs arising during the collaboration term. Arcus and Gilead are co-developing four investigational products, including zimberelimab (Arcus's anti-PD-1 molecule), domvanalimab (Arcus's anti-TIGIT antibody), etrumadenant (Arcus's adenosine

receptor antagonist) and quemliclustat (Arcus's CD73 inhibitor). The collaboration was expanded in November 2021 to include research directed to two targets for oncology, which research collaboration was further expanded in May 2023 to add up to four targets for inflammatory diseases.

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 partners, patients and physicians around the world, Arcus is expediting the development of first- or 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, dual A2a/A2b receptor and CD39), AXL and HIF-2a. For more information about Arcus Biosciences' clinical and pre-clinical programs, please visit **www.arcusbio.com** or follow us on Twitter.

Domvanalimab, etrumadenant, quemliclustat, and zimberelimab are investigational molecules, and neither Gilead nor Arcus has received approval from any regulatory authority for any use globally, and their safety and efficacy have not been established. Casdatifan, AB598 and AB801 are also investigational molecules, and Arcus has not received approval from any regulatory authority for any use globally, and their safety and efficacy have not been established.

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. Rosen's quote and statements regarding: Arcus's expectation that its cash, cash equivalents and marketable securities on-hand are sufficient to fund operations into 2027 and support Phase 3 trials for 3 different molecules and launch preparations; the timing and scope of analyses, data disclosures and presentations; whether data and results from current studies support further development of a program; expected timing of clinical milestones, including the completion of enrollment; our ability to accelerate the development of our clinical pipeline; the potential of casdatifan to achieve substantially greater HIF-2a inhibition than the approved dose of the marketed competitor; the potency, efficacy or safety of Arcus's investigational products; and the initiation of and associated timing for future studies, including STAR-131 and the Phase 3 studies in ccRCC and pancreatic cancer. 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 periodic report 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.

ARCUS BIOSCIENCES, INC.
Consolidated Statements of Operations
(unaudited)
(In millions, except per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenues:				
License and development service revenue	$ 22	$ 26	$ 80	$ 74
Other collaboration revenue	9	8	37	38
Total revenues	31	34	117	112
Operating expenses:				
Research and development	93	80	340	288
General and administrative	29	28	117	104
Total operating expenses	122	108	457	392
Loss from operations	(91)	(74)	(340)	(280)
Non-operating income (expense):				
Interest and other income, net	11	8	41	16
Effective interest on liability for sale of future royalties	—	(1)	(2)	(2)
Total non-operating income, net	11	7	39	14
Net loss before income taxes	(80)	(67)	(301)	(266)
Income tax expense	(1)	—	(6)	(1)
Net loss	$ (81)	$ (67)	$ (307)	$ (267)
Net loss per share:				
Basic and diluted	$ (1.08)	$ (0.93)	$ (4.15)	$ (3.71)
Shares used to compute net loss per share:				
Basic and diluted	75.0	72.6	74.0	72.0

Selected Consolidated Balance Sheet Data
(unaudited)
(In millions)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 866	$ 1,138
Total assets	1,095	1,345
Total liabilities	633	688
Total stockholders' equity	462	657

Derived from the audited financial statements included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 21, 2024.

Investor Inquiries:

Pia Eaves

Head of Investor Relations & Strategy

(617) 459-2006

peaves@arcusbio.com

Media Inquiries:

Holli Kolkey

VP of Corporate Communications

(650) 922-1269

hkolkey@arcusbio.com

Source: Arcus Biosciences