NEWS RELEASE

Arcus Biosciences Reports Fourth-Quarter and Full-Year 2022 Financial Results and Provides a Pipeline Update

2/28/2023

- At the American Society of Clinical Oncology (ASCO) Plenary session in December 2022, interim data were presented from the ARC-7 study, which demonstrated a median PFS of ~12.0 months for domvanalimab plus zimberelimab vs 5.4 months for zimberelimab alone.
- In 2022, Arcus and Gilead initiated several new clinical studies for domvanalimab, including two new registrational Phase 3 studies, for a total of four ongoing Phase 3 studies.
- Data from at least four clinical studies are anticipated in 2023, including updated ARC-7 data at the ASCO Annual Meeting in June and data from ARC-6 in prostate cancer and ARC-9 in colorectal cancer.
- Arcus is enrolling the second dose-escalation cohort (50mg) of ARC-20, a Phase 1/1b study of Arcus's small molecule HIF-2a inhibitor AB521; initial data for ARC-20 are anticipated in late 2023 or early 2024; a Phase 2 study evaluating AB521 in combination with other agents is anticipated for the second half of 2023.
- Arcus expects to submit IND filings for at least two molecules this year; Arcus also expects to advance its first molecule against an inflammation target, a highly selective KIT inhibitor, into the clinic by early 2024.
- With $1.1 billion in cash, cash equivalents, and marketable securities and funding into 2026, Arcus is well-positioned to advance its extensive pipeline.

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, 2022 and provided a pipeline

update on its six clinical-stage investigational molecules – targeting TIGIT, the adenosine axis (CD73 and A2a/A2b receptors), HIF-2a and PD-1 – across multiple common cancers.

“During 2022, Arcus established itself as a late-stage company and made tremendous progress in the advancement of its pipeline. This included the initiation of multiple registrational Phase 3 studies evaluating domvanalimab-based combinations versus standard of care, as well as the advancement of AB521, our HIF-2a inhibitor, into a Phase 1/1b study in patients,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “Importantly, we also presented an interim analysis of ARC-7 data in December, demonstrating the potential for our domvanalimab-based combination to be a best-in-class anti-TIGIT/anti-PD-1 combination. In 2023, we expect multiple Phase 1b and Phase 2 clinical readouts and advancement into the clinic of at least two new drug candidates. With $1.1 billion in cash and runway into 2026, we are well-positioned to establish Arcus as a leader in the development of innovative therapies for lung and GI cancers.”

Pipeline Highlights:

Domvanalimab (Fc-silent anti-TIGIT monoclonal antibody)

Domvanalimab Updates:

- In 2022, Arcus and Gilead advanced their broad development strategy for domvanalimab, which now includes eight ongoing Phase 2 and Phase 3 studies evaluating domvanalimab-based combinations in non-small cell lung cancer (NSCLC) and upper gastrointestinal (GI) cancers.
    - The companies now have four ongoing registrational Phase 3 studies: three of the studies are in multiple NSCLC settings (ARC-10, STAR-121 and Pacific-8) and one study is in upper GI cancer (STAR-221).
    - There are also four ongoing Phase 2 studies to evaluate domvanalimab-based combinations: three in NSCLC and one in upper GI cancer.
- Interim data from ARC-7, a 150-patient, randomized Phase 2 study evaluating the safety and efficacy of zimberelimab alone vs. domvanalimab plus zimberelimab (“doublet”) vs. domvanalimab plus zimberelimab and etrumadenant (“triplet”) in 1L PD-L1 ≥50% metastatic NSCLC, were presented on December 20, 2022 at the ASCO Monthly Plenary Series.
    - At the time of data cutoff, efficacy was evaluated in patients who started treatment at least 13 weeks prior and were therefore potentially eligible for at least two imaging scans (n=133).
    - With a median follow-up time of approximately 12 months, a doubling of median progression-free survival (mPFS) was observed in each of the doublet and triplet arms, compared to zimberelimab monotherapy. The doublet and triplet arms demonstrated 12.0 months and 10.9 months mPFS,

respectively, compared to 5.4 months observed in the zimberelimab monotherapy arm.
    - The doublet and triplet combinations demonstrated, respectively, a 45% and 35% reduction in risk of progression or death compared to zimberelimab monotherapy.
    - The domvanalimab-containing arms also demonstrated clinically meaningful improvements in six-month landmark PFS rates and objective response rate (ORR) compared to zimberelimab monotherapy.
    - Safety was evaluated in all enrolled patients who received at least one dose (n=149). No unexpected safety signals were observed across the three study arms at the time of data cutoff. The domvanalimab-containing study arms appeared to be generally well tolerated and showed an overall safety profile consistent with the known safety profiles of each individual molecule to date.
- During the fourth quarter, Taiho Pharmaceutical, Arcus's partner in Japan and other territories in Asia, opted to participate in two Phase 3 trials of domvanalimab combinations, STAR-121 in NSCLC and STAR-221 in upper GI cancer. Due to Taiho's participation, Arcus expects to receive certain milestone payments from Taiho in 2023.

Upcoming Domvanalimab Milestones:

- An updated analysis of the ARC-7 study, including efficacy evaluation for all 150 patients, is expected to be presented at the ASCO Annual Meeting in June 2023.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

Etrumadenant Updates:

- In the fourth quarter, Arcus and Gilead initiated VELOCITY-Lung, a Phase 2 platform study, operationalized by Gilead, which is evaluating domvanalimab-, etrumadenant-, and zimberelimab-based combinations in advanced NSCLC.

Upcoming Etrumadenant Milestones:

- Data from the randomized cohort of ARC-6, a Phase 1b/2 study evaluating etrumadenant plus zimberelimab and docetaxel versus docetaxel in metastatic castrate-resistant prostate cancer (CRPC), are expected in 2023.
- Data from ARC-9, a Phase 1b/2 study evaluating etrumadenant-based combinations in 2L and third-line (3L) metastatic colorectal cancer (mCRC), are expected in 2023.

Quemliclustat (small-molecule CD73 inhibitor)

Quemliclustat Updates:

- In the fourth quarter, Arcus and Gilead initiated EDGE-Lung, a Phase 2 platform study to evaluate

domvanalimab-, quemliclustat-, and zimberelimab-based combinations in advanced NSCLC.

Upcoming Quemliclustat Milestones:

- In the first half of 2023, Arcus and Gilead expect PFS and OS data from all 90 patients in the ongoing Phase 1/1b ARC-8 trial evaluating quemliclustat plus chemotherapy with or without zimberelimab in first-line pancreatic cancer.
- Arcus and Gilead expect to initiate one or more cohorts with quemliclustat-based combinations in GI cancers in the ongoing Phase 2 ARC-21 study.

AB521 (HIF-2 a inhibitor)

Upcoming AB521 Milestones:

- During the fourth quarter, Arcus completed Cohort 1 of ARC-20, a Phase 1/1b study of AB521 in cancer patients; at a dose level of 20 mg daily, deep reductions in serum erythropoietin were observed, which was consistent with observations from the ARC-14 study, evaluating AB521 in healthy volunteers.
    - Arcus is enrolling Cohort 2, evaluating a 50 mg daily dose, which Arcus believes may achieve greater drug levels than the marketed competitor.
    - Initial data from ARC-20 are anticipated in late 2023 or early 2024.
- A Phase 2 study evaluating AB521 in combination with other agents is anticipated for the second half of 2023.

Discovery Programs

- Arcus is on track to initiate a Phase 1 trial in cancer patients for AB598, its anti-CD39 antibody, in the first half of 2023.
- Arcus plans to initiate a Phase 1 trial for AB801, a potent and highly selective Axl inhibitor, in 2023. The early development plan is expected to focus on treatment-resistant tumor types, such as STK11-mutant NSCLC.
- Arcus expects to advance its first candidate against an inflammation target, AB375, a highly selective KIT inhibitor, into the clinic in early 2024.

Financial Results for the Fourth-Quarter and Full-Year 2022

- Cash, cash equivalents and marketable securities were $1.1 billion as of December 31, 2022, compared to $681 million as of December 31, 2021. The increase was primarily due to the receipt of $725 million from Gilead in January 2022. Arcus expects cash utilization for 2023 to be between $300 million and $350 million. Its cash, cash equivalents and marketable securities on-hand is expected to be sufficient to fund operations into 2026.

- Revenues were $34 million for the fourth-quarter 2022, compared to $355 million for the same period in 2021. In the fourth-quarter 2022, Arcus recognized $26 million in license and development service revenues for programs optioned by Gilead. Arcus further recognized $8 million in collaboration revenue related to Gilead's ongoing rights to access Arcus's research and development pipeline in accordance with the Gilead collaboration agreement. Revenues were $112 million for the full-year 2022, compared to $383 million for the same period in 2021.
- Research and Development (R&D) Expenses were $80 million for the fourth-quarter 2022, compared to $51 million for the same period in 2021. Arcus's expanding clinical and development activities increased costs by $60 million, partially offset by $31 million in higher reimbursements for shared expenses from Arcus's collaborations, primarily the Gilead collaboration, which was expanded in December 2021. The $29 million increase in R&D costs net of reimbursements was driven by Arcus's expanding clinical and development activities as Arcus enrolled more patients in its existing and new studies, which drove increases of $12 million in net clinical costs and $9 million in net manufacturing costs. Arcus's growing headcount drove a $5 million increase in net employee compensation costs. For fourth-quarter 2022 and 2021, Arcus recognized gross reimbursements of $49 million and $18 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration. For the full-year 2022 and 2021, R&D expenses were $288 million and $257 million, respectively. This includes gross reimbursements of $161 million and $25 million, respectively, for shared expenses from Arcus's collaborations, primarily the Gilead collaboration, which was expanded in December 2021.
- General and Administrative (G&A) Expenses were $28 million for the fourth-quarter 2022, compared to $23 million for the same period in 2021. The increase was driven by the increased complexity of supporting Arcus's expanding clinical pipeline and partnership obligations. Arcus's growing headcount and 2022 stock awards drove a $4 million increase in employee compensation costs, including a $2 million increase in non-cash stock-based compensation, as well as increases in office facilities due to the expansion of office space to support the higher headcount. G&A expenses were $104 million for the full-year 2022, compared to $72 million for the same period in 2021.
- Net Income (Loss): Net loss was $67 million for the fourth-quarter 2022, compared to a net income of $280 million for the same period in 2021. Net loss was $267 million for the full-year 2022, compared to a net income of $53 million for the same period in 2021.

Arcus Ongoing and Announced Clinical Studies

Trial Name	Arms	Setting	Status	NCT No.

Lung Cancer				
ARC-7	zim vs. dom + zim vs. etruma + dom + zim	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Randomized Phase 2	**NCT04262856**
PACIFIC-8 (Operationalized by AZ)	dom + durva vs. durva	Curative-Intent Stage 3 NSCLC	Ongoing Registrational Phase 3	**NCT05211895**
ARC-10	dom + zim vs. pembro	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Registrational Phase 3	**NCT04736173**
STAR-121 (Operationalized by GILD)	dom + zim + chemo vs. pembro + chemo	1L NSCLC (PD-L1 all-comers)	Ongoing Registrational Phase 3	**NCT05502237**
EDGE-Lung	dom +/- zim +/- quemli +/- chemo	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	**NCT05676931**
VELOCITY-Lung (Operationalized by GILD)	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 ± 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 (also enrolling sacituzumab govitecan-hziy combination cohorts)	2L/3L CRPC	Ongoing Randomized Phase 2	**NCT04381832**
Various				
ARC-12	AB308 + zim	Advanced Malignancies	Ongoing Phase 1/1b	**NCT04772989**
ARC-14	AB521	Healthy Volunteers	Ongoing	**NCT05117554**
ARC-20	AB521	Cancer Patients / ccRCC	Ongoing Phase 1/1b	**NCT05536141**

dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; nivo: nivolumab; pembro: pembrolizumab; quemli: quemliclustat; SOC: standard-of-care; 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, Gilead and Arcus entered into a 10-year collaboration that provided Gilead immediate rights to zimberelimab and the right to opt into all other Arcus programs arising during the collaboration term. In November 2021, Gilead and Arcus amended the collaboration in connection with Gilead's option exercise for three of Arcus's then-clinical stage programs. For all other programs that are in clinical development or new programs that enter clinical development thereafter, the opt-in payments are $150 million per program. Gilead's option, on a program-by-program basis, expires after a specified period of time following the achievement of a development milestone for such program and Arcus's delivery to Gilead of the requisite qualifying data package. Concurrent with the May 2020 collaboration agreement, Gilead and Arcus entered into a stock purchase agreement under which Gilead made a $200 million equity investment in Arcus. That stock purchase agreement was amended and restated in February 2021 in connection with Gilead's increased equity stake in Arcus from 13% to 19.5%, with an additional $220 million investment.

Pursuant to the collaboration, Gilead and Arcus are currently co-developing and equally sharing global development costs for five clinical candidates, including: domvanalimab, an Fc-silent anti-TIGIT antibody; etrumadenant, a dual adenosine A2a/A2b receptor antagonist; quemliclustat, a small molecule inhibitor of CD73; and zimberelimab, an anti-PD1 antibody.

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 six investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis (CD73 and dual A2a/A2b receptor) 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. AB521 and AB598 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, including, but not limited to, the statements in Dr. Rosen's quote, Arcus's expectation that its cash, cash equivalents and marketable securities on-hand are sufficient to fund operations into 2026, future data disclosures and presentations, the projected achievement of clinical study milestones and their associated timing (including under the captions "Upcoming Domvanalimab Milestones," "Upcoming Etrumadenant Milestones," "Upcoming Quemliclustat Milestones," and "Upcoming AB521 Milestones"), additional clinical studies in planning or expected to be initiated (including under the caption "Discovery Programs"), and the receipt and timing of milestone payments from Taiho 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 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, all of which may be exacerbated by the COVID-19 pandemic; 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 its Annual Report on Form 10-K for the year ended December 31, 2022, filed on February 28, 2023 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 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,	
	2022	2021	2022	2021
Revenues:				
License and development service revenue	$ 26	$ 345	$ 74	$ 345
Other collaboration revenue	8	10	38	38
Total revenues	34	355	112	383
Operating expenses:				
Research and development	80	51	288	257
General and administrative	28	23	104	72
Total operating expenses	108	74	392	329
Income (loss) from operations	(74)	281	(280)	54
Non-operating income (expense):				
Interest and other income, net	8	1	16	1
Effective interest on liability for sale of future royalties	(1)	-	(2)	-
Total non-operating income, net	7	1	14	1
Income (loss) before income taxes	(67)	282	(266)	55
Income tax expense	-	(2)	(1)	(2)
Net income (loss)	$ (67)	$ 280	$ (267)	$ 53
Net income (loss) per share:				
Basic	$ (0.93)	$ 3.97	$ (3.71)	$ 0.76
Diluted	$ (0.93)	$ 3.71	$ (3.71)	$ 0.71
Shares used to compute net income (loss) per share:				
Basic	72.6	70.4	72.0	69.3
Diluted	72.6	75.4	72.0	74.0

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 1,138	$ 681
Total assets	1,345	1,592
Total liabilities	688	750
Total stockholders' equity	657	842

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