NEWS RELEASE

Arcus Biosciences Reports First Quarter 2023 Financial Results and Provides a Pipeline Update

5/9/2023

- Four Phase 3 and two Phase 2 trials are now enrolling to evaluate domvanalimab-based combinations in lung and gastrointestinal cancers.
- The third dose-escalation cohort (100mg) of ARC-20 for AB521, a potential best-in-class HIF-2a inhibitor, is enrolling; the dose-expansion stage of ARC-20 and a Phase 2 combination study in clear-cell renal cell carcinoma (ccRCC) patients are expected to begin in the third quarter.
- Three new drug candidates are expected to advance into the clinic in 2023 and early 2024.
- With $1.0 billion in cash, cash equivalents and marketable securities and funding into 2026, Arcus is well-positioned to advance its 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 first quarter ended March 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 and PD-1 – across multiple common cancers.

“Together with our partner Gilead, we continue to execute on our four Phase 3 studies evaluating domvanalimab-based combinations versus standard of care in lung and gastrointestinal cancers. We are also making great progress on our earlier-stage pipeline. Specifically, we plan to initiate a Phase 2 combination study for AB521, our potential best-in-class HIF-2a inhibitor, in the second half of this year, while also advancing two additional molecules into the clinic in 2023,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “Meanwhile, we are

leveraging our deep immunology and small-molecule expertise to diversify our portfolio into inflammatory disease with the advancement of our KIT inhibitor program. With $1.0 billion in cash and investments and runway into 2026, we are in an extremely strong position to advance our diverse portfolio of innovative therapies."

Pipeline Highlights:

Domvanalimab (Fc-silent anti-TIGIT monoclonal antibody)

- Data from the ARC-7 study will be presented during the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023, which will include updated data for all 150 patients in the trial.
- Initial ORR data from the ongoing EDGE-Gastric (ARC-21) Phase 2 study of domvanalimab plus zimberelimab in first- and second-line upper GI cancers are expected in the second half of 2023. These data will be from the cohort that reflects the same patient population and dosing regimen as the ongoing Phase 3 study, STAR-221.

AB521 (HIF-2a inhibitor)

- Arcus is enrolling the third dose-escalation cohort of ARC-20, a Phase 1/1b study of AB521 in cancer patients, evaluating a 100-mg daily dose, which Arcus believes has the potential to achieve at least 3 times greater HIF-2a inhibition than that of the approved dose of the marketed competitor.
    - Upon completion of this cohort, Arcus expects to advance ARC-20 into the dose-expansion stage of the study.
    - Initial pharmacokinetic (PK), pharmacodynamic (PD) and safety data, along with any preliminary signs of anti-tumor activity from the dose-escalation phase of ARC-20, are anticipated in late 2023 or early 2024.
- A Phase 2 study evaluating AB521 in combination with other agents is anticipated to begin in the third quarter of 2023.

Quemliclustat (small-molecule CD73 inhibitor)

- Arcus and Gilead expect mature overall survival (OS) data from the ongoing Phase 1/1b ARC-8 trial evaluating quemliclustat plus chemotherapy with or without zimberelimab in first-line pancreatic cancer in the second half of 2023; these data will inform next steps for quemliclustat in pancreatic cancer.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

- Updated analysis from the ARC-7 study will be presented at the ASCO Annual Meeting in June 2023, including more mature data for the etrumadenant plus domvanalimab plus zimberelimab arm.
- 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 (mCRPCs), are expected in the

second half of 2023.

- Data from ARC-9, a Phase 1b/2 study evaluating etrumadenant plus zimberelimab plus chemotherapy in second-line and third-line metastatic colorectal cancer (mCRC), are expected in the second half of 2023.

Preclinical Programs

- The IND for AB598, Arcus's anti-CD39 antibody, has been cleared by the FDA, and Arcus is on track to initiate a Phase 1 trial in cancer patients in the second quarter of 2023.
- Arcus expects to initiate a Phase 1 study for AB801, a potent and highly selective Axl inhibitor, in the second half of 2023.
    - Arcus presented data at the American Association for Cancer Research (AACR) Annual Meeting in April 2023 demonstrating high potency and selectivity of AB801 for Axl over other kinases in multiple assays; the data also showed that AB801 significantly decreased tumor volume and increased survival in mouse tumor models.
    - 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 First Quarter 2023:

- Cash, cash equivalents and marketable securities were $1.0 billion as of March 31, 2023, compared to $1.1 billion as of December 31, 2022. The decrease during the period is primarily due to the use of cash in research and development activities. Cash, cash equivalents and marketable securities on-hand are expected to be sufficient to fund operations into 2026.
- Revenues were $25 million for first quarter 2023, compared to $18 million for the same period in 2022. In first quarter 2023, Arcus recognized $17 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.
- Research and Development (R&D) Expenses were $81 million for first quarter 2023, compared to $61 million for the same period in 2022. Arcus's expanding clinical and development activities increased costs by $31 million, partially offset by $11 million in higher reimbursements for shared expenses from Arcus's collaborations, primarily the Gilead collaboration, which was expanded in December 2021. The $20 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. Non-cash stock-based compensation

expense was $9 million for both periods. For first-quarter 2023 and 2022, Arcus recognized reimbursements of $42 million and $31 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration.

- General and Administrative (G&A) Expenses were $30 million for first quarter 2023, compared to $24 million for the same period in 2022. The increase was driven by the increased complexity of supporting Arcus's expanding clinical pipeline and partnership obligations. Non-cash stock-based compensation expense was $10 million for first quarter 2023, compared to $8 million for the same period in 2022.
- Net Loss was $80 million for first quarter 2023, compared to $68 million for the same period in 2022.

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 Gilead)	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 Gilead)	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 (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 in to 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 multiple 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 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 2026; the timing and scope of future data disclosures and presentations; the efficacy or safety of Arcus's investigational products and the initiation of and associated timing for future studies. 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 its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed on May 9, 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 March 31,

	2023	2022
Revenues:		
License and development service revenue	$ 17	$ 8
Other collaboration revenue	8	10
Total revenues	25	18
Operating expenses:		
Research and development	81	61
General and administrative	30	24
Total operating expenses	111	85
Loss from operations	(86)	(67)
Non-operating income (expense):		
Interest and other income, net	9	-
Effective interest on liability for sale of future royalties	(1)	-
Total non-operating income, net	8	-
Net loss before income taxes	(78)	(67)
Income tax expense	(2)	(1)
Net loss	$ (80)	$ (68)
Net loss per share:		
Basic and diluted	$ (1.09)	$ (0.96)
Shares used to compute net loss per share:		
Basic and diluted	73.0	71.2

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

	March 31, 2023	December 31, 2022(1)
Cash, cash equivalents and marketable securities	$ 1,044	$ 1,138
Total assets	1,254	1,345
Total liabilities	654	688
Total stockholders' equity	600	657

(1) Derived from the audited financial statements for the quarter ended December 31, 2022, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2023.

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