NEWS RELEASE

Arcus Biosciences Reports Second-Quarter 2024 Financial Results and Provides a Pipeline Update

8/8/2024

- Data from the casdatifan 100 mg expansion cohort of ARC-20, a Phase 1/1b study in clear cell renal cell carcinoma (ccRCC), are expected to be presented at a medical conference in the fourth quarter of 2024
- PEAK-1, the initial Phase 3 study evaluating casdatifan in combination with cabozantinib, is expected to begin in the first half of 2025
- Patient enrollment has completed for the Phase 3 study STAR-221 (upper gastrointestinal (GI) cancers) for domvanalimab plus zimberelimab and chemotherapy
- Arcus is well-positioned to advance its full pipeline with $1.0 billion in cash, cash equivalents and marketable securities and runway into 2027
- 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 second quarter ended June 30, 2024, 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.

“Our upcoming presentation of efficacy and safety data for casdatifan will demonstrate that it has the potential to be the best-in-class HIF-2a inhibitor,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “We are pursuing a broad development program in both first- and second-line settings, as well as differentiated combinations, to maximize the opportunity for casdatifan in ccRCC. Meanwhile, the accumulating data continue to enhance our confidence that our Fc-silent anti-TIGIT antibody, domvanalimab, has the potential for an improved safety profile

over that of Fc-enabled antibodies, particularly when combined with chemotherapy, which may also result in an efficacy advantage for domvanalimab. With STAR-221 enrollment completed, we are looking forward to our first Phase 3 data readout."

Corporate Updates:

- In July 2024, Taiho Pharmaceutical (Taiho) exercised its option for quemliclustat, an investigational small molecule CD73 inhibitor, in Japan and certain other territories in Asia (excluding mainland China). As a result of this option exercise, Taiho will operationalize the Phase 3 PRISM-1 study evaluating quemliclustat in pancreatic cancer in Japan, and Arcus will receive an opt-in payment and is eligible to receive near-term milestone payments.

Pipeline Highlights:

Casdatifan (HIF-2a inhibitor)

- Multiple expansion cohorts evaluating casdatifan in clear cell renal cell carcinoma (ccRCC) are underway, with several data presentations expected in the next 18 months. Each cohort is enrolling approximately 30 patients.
    - ARC-20: Phase 1/1b study evaluating casdatifan as a monotherapy and in combination with other agents:
        - 100 mg daily expansion cohort in 2L+ ccRCC: ORR data are expected to be presented in the fourth quarter of 2024.
        - 50 mg and 150 mg expansion cohorts in 2L+ ccRCC: Enrollment has been completed for both cohorts and data are expected to be presented in 2025.
        - An expansion cohort evaluating casdatifan in combination with cabozantinib in 2L+ ccRCC is also enrolling.
- Following FDA feedback later this year, Arcus plans to initiate its first Phase 3 study, PEAK-1, evaluating casdatifan in combination with cabozantinib versus cabozantinib monotherapy in patients with metastatic ccRCC who have previously received anti-PD-1 therapy, in the first half of 2025.
- Arcus is in advanced stages of planning with a clinical collaboration partner to evaluate casdatifan in a potential first-in-class combination regimen for first-line metastatic ccRCC.

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

Domvanalimab-Zimberelimab Updates:

- Updated data presented at the ASCO Annual Meeting from Arm A1 of the Phase 2 EDGE-Gastric study showed

12.9 months median progression-free survival (PFS) for domvanalimab plus zimberelimab and chemotherapy in first-line upper GI adenocarcinomas, which exceeded historical benchmarks for anti-PD-1 plus chemotherapy.
    - The EDGE-Gastric study is evaluating the same regimen in the same setting as the STAR-221 Phase 3 study.

- STAR-221, a Phase 3 study evaluating domvanalimab plus zimberelimab and chemotherapy in PD-L1 all-comer first-line metastatic upper GI adenocarcinomas, completed enrollment in June.
- STAR-121, a Phase 3 study evaluating domvanalimab plus zimberelimab and chemotherapy in PD-L1 all-comer first-line metastatic non-small cell lung cancer (NSCLC), is expected to complete enrollment in 2024.

Upcoming Domvanalimab-Zimberelimab Milestones:

- Overall survival (OS) and PFS data from previously enrolled patients in Part 1 of the Phase 3 ARC-10 study, evaluating domvanalimab plus zimberelimab versus zimberelimab versus chemotherapy in first-line PD-L1-high NSCLC, are expected to be presented by the end of 2024.
- OS data from the Phase 2 EDGE-Gastric study, evaluating domvanalimab plus zimberelimab and chemotherapy in upper GI adenocarcinomas, are expected to be presented in 2025.

CD73-Adenosine Axis: Etrumadenant (A2a/A2b receptor antagonist) and Quemliclustat (small-molecule CD73 inhibitor)

Etrumadenant

- Cohort B data from ARC-9, a randomized Phase 1b/2 study evaluating etrumadenant plus zimberelimab, FOLFOX chemotherapy and bevacizumab (EZFB) versus regorafenib in third-line metastatic colorectal cancer (mCRC), were presented at ASCO in June.
    - Results showed 19.7 months median OS for the EZFB arm, and EZFB significantly reduced the risk of death by 63% and risk of disease progression by 73% compared to regorafenib. This is the longest median OS reported in third-line mCRC to date in a randomized trial.
    - Biomarker data from this study are expected to be presented at a scientific conference in the second half of 2024.
- Based on these encouraging results, Arcus and Gilead are determining next steps for the development of etrumadenant in mCRC.

Quemliclustat

- Initiation of a Phase 3 trial, PRISM-1, of quemliclustat combined with gemcitabine/nab-paclitaxel versus

gemcitabine/nab-paclitaxel in pancreatic cancer is expected to begin by early 2025.
- Taiho exercised its option for an exclusive license to quemliclustat in Japan and certain territories in Asia and will operationalize PRISM-1 in Japan.

Early Clinical Programs

- Dose escalation for AB801, a potent and highly selective small-molecule AXL inhibitor, continues. Arcus anticipates advancing this molecule into expansion cohorts in NSCLC in early 2025.

Financial Results for Second Quarter 2024:

- Cash, Cash Equivalents and Marketable Securities were $1.0 billion as of June 30, 2024, compared to $866 million as of December 31, 2023. The increase during the period is primarily due to the receipt of $320 million in cash from Gilead for their January 2024 equity investment, partially offset by the use of cash in research and development activities. We believe our cash, cash equivalents and marketable securities on-hand will be sufficient to fund operations into 2027. Cash, cash equivalents and marketable securities are expected to be between $885 million and $925 million at the end of 2024.
- Revenues were $39 million for the second quarter 2024, compared to $29 million for the same period in 2023. In the second quarter 2024, Arcus recognized $28 million in license and development services revenue related to the advancement of programs, as well as $11 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.
- Research and Development (R&D) Expenses were $115 million for the second quarter 2024, compared to $84 million for the same period in 2023. The net increase of $31 million was primarily driven by higher clinical trial and headcount-related costs associated with our late-stage development program activities. Non-cash stock-based compensation expense was $10 million for the second quarter 2024, compared to $9 million for the same period in 2023. For the second quarter 2024 and 2023, Arcus recognized gross reimbursements of $40 million and $44 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration. 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 $30 million for the second quarter 2024, compared to $28 million for the same period in 2023. The increase was primarily driven by higher headcount and costs incurred to obtain the Third Gilead Agreement Amendment. Non-cash stock-based compensation expense was $10 million for the second quarter 2024, compared to $9 million for the same period in 2023.
- Net Loss was $93 million for the second quarter 2024, compared to $75 million for the same period in 2023.

Conference Call Information:

Arcus will host a conference call and webcast today, August 8, at 2:00 PM PT / 5:00 PM ET to discuss its second-quarter 2024 financial results and pipeline updates. To access the call, please dial (404) 975-4839 (local) or (833) 470-1428 (toll-free), using Access Code: 287576. 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				
STAR-121	dom + zim + chemo vs. pembro + chemo	1L NSCLC (PD-L1 all-comers)	Ongoing Registrational Phase 3	**NCT05502237**
PACIFIC-8	dom + durva vs. durva	Unresectable Stage 3 NSCLC	Ongoing Registrational Phase 3	**NCT05211895**
STAR-131	dom + zim + chemo; dom + zim	Perioperative NSCLC	Registrational Phase 3 In Planning	TBD
ARC-7	zim vs. dom + zim vs. etruma + dom + zim	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Randomized Phase 2	**NCT04262856**
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**
Upper Gastrointestinal Cancers				
STAR-221	dom + zim + chemo vs. nivo + chemo	1L Gastric, GEJ and EAC	Ongoing Registrational Phase 3	**NCT05568095**
EDGE-Gastric (ARC-21)	dom +/- zim +/- quemli +/- chemo	1L/2L Upper GI Malignancies	Ongoing Randomized Phase 2	**NCT05329766**
Colorectal Cancer				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	**NCT04660812**
Pancreatic Cancer				
PRISM-1	quemli + gem/nab-pac vs. gem/nab-pac	1L PDAC	Planned Phase 3	TBD
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L, 2L PDAC	Ongoing Randomized Phase 1/1b	**NCT04104672**
Kidney Cancer				
PEAK-1	cas + cabo vs. cabo	Post-IO ccRCC	Planned Phase 3	TBD
STELLAR-009	cas + zanza	ccRCC	Ongoing Phase 1b/2	**NCT06191796**
ARC-20	cas, cas + cabo	Cancer Patients / ccRCC	Ongoing Phase 1/1b	**NCT05536141**
Other				
ARC-25	AB598	Advanced Malignancies	Ongoing	**NCT05891171**
ARC-27	AB801	Advanced Malignancies	Ongoing	**NCT06120075**

cabo: cabozantinib; 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; EAC: esophageal adenocarcinoma; GEJ: gastroesophageal junction; 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 and May 2023 to include research directed to two targets for oncology and two 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 collaborators, 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), **HIF-2a** , **CD39** , and **AXL** . For more information about Arcus Biosciences' clinical and preclinical programs, please visit **www.arcusbio.com** .

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; plans to disclose or present study analyses or data, including any analyses or data from ARC-20, EDGE-Gastric, or ARC-10; whether data and results from studies validate our pipeline or support further development of a program; the potency, efficacy or safety of Arcus's investigational products, including their potential for a best-in-class profile; and the initiation of and associated timing for future studies, including statements about PEAK-1 and PRISM-1. 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 in Arcus's investigational products; 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; unfavorable global economic, political and trade conditions; Arcus's dependence on the collaboration with third parties such as Gilead and Taiho 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
License and development services revenue	$ 28	$ 19	$ 163	$ 36
Other collaboration revenue	11	10	21	18
Total revenues	39	29	184	54
Operating expenses:				
Research and development	115	84	224	165
General and administrative	30	28	62	58
Impairment of long-lived assets	—	—	20	—
Total operating expenses	145	112	306	223
Loss from operations	(106)	(83)	(122)	(169)
Non-operating income (expense):				
Interest and other income, net	13	9	26	18
Effective interest on liability for sale of future royalties	—	—	(1)	(1)
Total non-operating income, net	13	9	25	17
Loss before income taxes	(93)	(74)	(97)	(152)
Income tax expense	—	(1)	—	(3)
Net loss	$ (93)	$ (75)	$ (97)	$ (155)
Net loss per share:				
Basic and diluted	$ (1.02)	$ (1.04)	$ (1.09)	$ (2.13)
Shares used to compute net loss per share:				
Basic and diluted	91.1	73.2	88.6	73.1

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

	June 30, 2024	December 31, 2023 (1)
Cash, cash equivalents and marketable securities	$ 1,009	$ 866
Total assets	1,186	1,095
Total liabilities	551	633
Total stockholders' equity	635	462

(1)Derived from the audited financial statements for the quarter ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 21, 2024.

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