NEWS RELEASE

Arcus Biosciences Reports Fourth-Quarter and Full-Year 2024 Financial Results and Provides a Pipeline Update

2025-02-25

- New data from the Phase 1/1b ARC-20 study showed that casdatifan improved upon the rate of primary progression, overall response rate (ORR) and progression-free survival (PFS) relative to published data from studies with HIF-2a inhibitors to date
- Initiation of the Phase 3 study for PEAK-1 evaluating casdatifan in combination with cabozantinib versus cabozantinib in immuno-oncology (IO)-experienced patients with clear cell renal cell carcinoma (ccRCC) is expected in the first half of 2025; initial data from the cohort of ARC-20 evaluating casdatifan plus cabozantinib are expected to be presented in mid-2025
- Arcus completed a $150 million financing and continues to be well positioned to advance its pipeline with $992 million in cash, cash equivalents and marketable securities as of December 31, 2024 (excluding proceeds from the offering)

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for patients with cancer, today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided a pipeline update on its clinical-stage investigational molecules across multiple common cancers.

“Last week, we presented data from nearly 90 ccRCC patients demonstrating casdatifan’s potential best-in-class

profile," said Terry Rosen, Ph.D., chief executive officer of Arcus. "Given the strong efficacy and preferable safety profile relative to standard-of-care VEGFR tyrosine kinase inhibitors, we believe casdatifan can play an important role in the treatment of every patient diagnosed with ccRCC. Arcus now has full developmental and commercial control of casdatifan, and we are pursuing a robust development plan in multiple ccRCC settings, which include our first Phase 3 trial, PEAK-1, expected to initiate next quarter, as well as our clinical collaboration with AstraZeneca. We are extremely well capitalized to execute on these plans, and we continue to evaluate and pursue opportunities to conserve capital and allocate greater resources to maximizing the potential of casdatifan."

Pipeline Highlights:

Casdatifan (HIF-2a inhibitor)

Casdatifan Updates:

- New clinical data from three monotherapy expansion cohorts in ARC-20 were presented in a rapid oral session at the 2025 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium in February. At the time of data cut-off (DCO, January 3, 2025), the efficacy-evaluable population included a total of 87 patients with ccRCC who had received at least two prior lines of therapy, including both an anti-PD-1 and a VEGFR tyrosine kinase inhibitor (TKI) therapy. These data support the potential for casdatifan to be a best-in-class HIF-2a inhibitor for the treatment of ccRCC:
    - Despite limited follow-up, two of the cohorts exceeded 30% confirmed ORR (inclusive of one partial response that confirmed after the DCO)
    - Rates of primary progressive disease (progression at or before their first disease assessment) ranged from 14% to 19%
    - Most patients (81-87%) experienced disease control with either a partial response or stable disease
    - Only two confirmed responders out of the 26 across all cohorts had discontinued due to progression, indicating the potential for a long duration of response
    - A 9.7-month median PFS was reached for the 50mg twice-daily casdatifan monotherapy cohort; median PFS was not yet reached for other cohorts
    - No unexpected safety signals were observed at the time of DCO, and casdatifan had an acceptable and manageable safety profile across all doses

Planned Data Readouts:

- Mid-2025: Safety and initial efficacy data for the ARC-20 cohort evaluating casdatifan plus cabozantinib in IO-experienced patients.
- Fall 2025: More mature data from the cohorts evaluating casdatifan monotherapy in patients who had

progressed on both an anti-PD-1 and a TKI therapy.
- 2026: More mature data from the casdatifan + cabozantinib cohort and initial data from the new ARC-20 cohorts evaluating casdatifan in the first-line (1L) and IO-experienced settings.

Upcoming Study and Cohort Initiations:

- Three new expansion cohorts within ARC-20 will be initiated in the first quarter of 2025:
  - Casdatifan plus zimberelimab in all-comer 1L ccRCC
  - Casdatifan monotherapy in favorable-risk 1L ccRCC
  - Casdatifan monotherapy in the IO-experienced setting for patients with ccRCC who have not received a VEGFR-TKI therapy
- The Phase 3 PEAK-1 study evaluating casdatifan in combination with cabozantinib versus cabozantinib in IO-experienced ccRCC is expected to initiate in the second quarter of 2025.
- A Phase 1b study, part of AstraZeneca's eVOLVE portfolio of trials, evaluating casdatifan in combination with volrustomig, AstraZeneca's investigational PD-1/CTLA-4 bispecific antibody, in IO-naive patients, is expected to initiate in 2025. AstraZeneca is operationalizing this study.

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

- Overall survival data from the Phase 2 EDGE-Gastric study, evaluating domvanalimab plus zimberelimab and chemotherapy in upper gastrointestinal (GI) adenocarcinomas, are expected to be presented in the fall of 2025.
- The first Phase 3 data readout for domvanalimab plus zimberelimab will be from the ongoing Phase 3 study STAR-221 evaluating domvanalimab plus zimberelimab and chemotherapy in PD-L1 all-comer 1L metastatic upper GI adenocarcinomas and is expected in 2026.

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

Quemliclustat:

- In the fourth quarter of 2024, Arcus initiated PRISM-1, a Phase 3 trial of quemliclustat combined with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel in pancreatic cancer. In February 2025, Arcus's partner, Taiho, dosed their first patient in Japan for PRISM-1.

Etrumadenant:

- Arcus plans to meet with the FDA in the first half of 2025 to clarify next steps for ARC-9, evaluating etrumadenant plus zimberelimab, FOLFOX, chemotherapy and bevacizumab (EZFB) versus regorafenib in

third-line metastatic colorectal cancer (mCRC).

Early Clinical Programs

- Evaluation of AB801, a potent and highly selective small-molecule AXL inhibitor, in the dose-escalation phase of a Phase 1/1b study in patients is ongoing. Arcus anticipates advancing this molecule into expansion cohorts in non-small cell lung cancer (NSCLC) in the second half of 2025.

Financial Results for Fourth Quarter and Full Year 2024:

- Cash, Cash Equivalents and Marketable Securities were $992 million as of December 31, 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, the receipt of the $100 million option continuation payment from Gilead in July 2024 and proceeds from our $50 million term loan, partially offset by the use of cash in research and development activities. Arcus expects its cash and investments, together with the proceeds from the equity financing in February 2025, will provide funding through our initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan including STAR-221, PRISM-1 and PEAK-1.
- Revenues were $36 million for the fourth quarter 2024, compared to $31 million for the same period in 2023. In the fourth quarter 2024, Arcus recognized $28 million in License and development service revenues related to the advancement of programs under the Gilead collaboration, as well as $8 million in Other 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) Expenseswere $111 million for the fourth quarter 2024, compared to $93 million for the same period in 2023. The net increase of $18 million was primarily driven by higher costs associated with our early-stage R&D and preclinical program activities, driven by higher enrollment in our studies for casdatifan, higher expense incurred on Gilead-led studies for domvanalimab, as well as increases in compensation cost related to our growing headcount. Non-cash stock-based compensation expense was $9 million for each of the fourth quarter 2024 and 2023. For the fourth quarter 2024 and 2023, Arcus recognized gross reimbursements of $41 million and $42 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration. Gross reimbursements were $165 million for the full year 2024, compared to $162 million for 2023. Our partnership reimbursements were flat compared to the prior year despite the increases in gross costs, due to increases in Gilead-led activities and programs fully funded by us. 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) Expenseswere $28 million for the fourth quarter 2024, compared to $29 million for the same period in 2023. Non-cash stock-based compensation expense was $8 million for the fourth quarter 2024, compared to $9 million for the same period in 2023.

- Net Losswas $94 million for the fourth quarter 2024, compared to $81 million for the same period in 2023.

Arcus Ongoing and Announced Clinical Studies:

Trial Name	Arms	Setting	Status	NCT No.
Kidney Cancer				
PEAK-1	cas + cabo vs. cabo	Post-IO ccRCC	Planned Phase 3	TBD
AstraZeneca Collaboration (part of eVOLVE portfolio)	cas + volru	2L+ IO-Naive ccRCC	Planned Phase 1b	TBD
ARC-20	cas, cas + cabo	2L+ Cancer Patients/ccRCC	Ongoing Phase 1/1b	**NCT05536141**
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 +/- chemo	1L/2L Upper GI Malignancies	Ongoing Randomized Phase 2	**NCT05329766**
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**
EDGE-Lung	dom +/- zim +/- quemli +/- chemo	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	**NCT05676931**
VELOCITY-Lung	dom +/- zim +/- sacituzumab govitecan-hziy or other combos	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	**NCT05633667**
Pancreatic Cancer				
PRISM-1	quemli + gem/nab-pac vs. gem/nab-pac	1L PDAC	Ongoing Randomized Phase 3	**NCT06608927**
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L PDAC	Ongoing Randomized Phase 1/1b	**NCT04104672**
Colorectal Cancer				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	**NCT04660812**
Other				
ARC-25	AB598	Gastric Cancer	Ongoing Phase 1	**NCT05891171**
ARC-27	AB801	NSCLC	Ongoing Phase 1	**NCT06120075**

cabo: cabozantinib; cas: casdatifan; ccRCC: clear cell renal cell carcinoma; CRC: colorectal cancer; dom: domvanalimab; durva: durvalumab; EAC: esophageal adenocarcinoma; etruma: etrumadenant; GEJ: gastroesophageal junction; gem/nab-pac: gemcitabine/nab-paclitaxel; GI: gastrointestinal; nivo: nivolumab; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma; pembro: pembrolizumab; quemli: quemliclustat; SOC: standard of care; zim: zimberelimab

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, HIF-2a, CD73, A2a/A2b receptors, CD39 and AXL. For more information about Arcus Biosciences's 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.

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.

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 and investments are sufficient to provide funding through its initial pivotal readouts for domvanalimab, quemliclustat and casdatifan; the timing of future study milestones, including the expected timing for data readout for STAR-221 and plans to disclose or present study analyses or data, including any analyses or data from ARC-20 or EDGE-Gastric; 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, design of and associated timing for future studies and cohorts, including statements about PEAK-1 and the new cohorts in ARC-20. 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 December 31,		Years Ended December 31,	
	2024	2023	2024	2023
Revenues:				
License and development service revenue	$28	$22	$222	$80
Other collaboration revenue	8	9	36	37
Total revenues	36	31	258	117
Operating expenses:				
Research and development	111	93	448	340
General and administrative	28	29	120	117
Impairment of long-lived assets	—	—	20	—
Total operating expenses	139	122	588	457
Loss from operations	(103)	(91)	(330)	(340)
Non-operating income (expense):				
Interest and other income, net	12	11	52	41
Interest expense	(2)	—	(4)	(2)
Total non-operating income, net	10	11	48	39
Loss before income taxes	(93)	(80)	(282)	(301)
Income tax expense	(1)	(1)	(1)	(6)
Net loss	$(94)	$(81)	$(283)	$(307)
Net loss per share:				
Basic and diluted	$(1.03)	$(1.08)	$(3.14)	$(4.15)
Shares used to compute net loss per share:				
Basic and diluted	91.7	72.6	90.1	74.0

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$992	$866
Total assets	1,150	1,095
Total liabilities	665	633
Total stockholders' equity	485	462

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 25, 2025.

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