NEWS RELEASE

Arcus Biosciences Reports First Quarter 2022 Financial Results and Provides a Pipeline Update, Including from the Third Interim Analysis for the ARC-7 Study

5/9/2022

- In a third interim analysis for the randomized Phase 2 ARC-7 study, both anti-TIGIT domvanalimab-containing arms continued to show meaningful differentiation compared to the anti-PD1 antibody zimberelimab alone when given as a treatment for first-line metastatic non-small cell lung cancer (NSCLC); we expect to provide a data update in 2H2022
- Arcus and Gilead continue to expand their late-stage clinical program for domvanalimab with the goal of establishing a best-in-class PD-1 + TIGIT antibody backbone and triplet regimens
- The third registrational Phase 3 study, STAR-121, will evaluate the combination of domvanalimab plus zimberelimab and chemotherapy versus standard of care pembrolizumab with chemotherapy in first-line NSCLC PD-L1 all-comers; expected to initiate in 4Q 2022
- Arcus is well positioned to advance its programs, including four registrational Phase 3 trials, with $1.3 billion in cash and cash equivalents and funding into 2026

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, 2022 and provided a pipeline update on its six clinical-stage molecules targeting TIGIT, the adenosine axis (CD73 and dual A2a/A2b receptor), HIF-2a and PD-1 across multiple common cancers. In addition, today Arcus announced encouraging results from the third interim analysis of the ongoing Phase 2 ARC-7 study. In this interim analysis, both domvanalimab-containing arms continued to show meaningful differentiation compared to zimberelimab alone across multiple efficacy measures,

including overall response rate (ORR) and duration of response (DoR). The clinical activity of zimberelimab alone was in line with established anti-PD-1 therapies in this patient population. At the time of data cut off, no unexpected safety signals were observed.

“We are optimistic about the potential for and committed to the goal of domvanalimab becoming a best-in-class anti-TIGIT antibody,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “The results from our most recent interim analysis further support the significant investment we and Gilead are making in the domvanalimab program, which is on track to increase from two ongoing to four Phase 3 studies by year-end and include expansion into new areas of unmet need with broader populations in lung and upper gastrointestinal cancers. Moreover, with a strong cash balance and six clinical-stage molecules across multiple cancer types, we are well-positioned to develop potentially practice-changing therapies for cancer patients in need of better treatment options.”

Anti-TIGIT program (domvanalimab and AB308)

Update on ARC-7:

- Arcus conducted a third interim analysis (IA3) for ARC-7, a randomized Phase 2 study evaluating the safety and efficacy of zimberelimab alone vs. domvanalimab plus zimberelimab (doublet) vs. domvanalimab plus zimberelimab and etrumadenant (triplet) as a first-line treatment for metastatic NSCLC PD-L1 TPS≥50% with no actionable mutations. The study has a target total enrollment of 150 patients who are being randomized 1:1:1 across three study arms and treated until disease progression or loss of clinical benefit.
- ARC-7 is an ongoing study and the data continues to mature as more patients are enrolled and patients are followed for longer durations.
- Gilead and Arcus are co-developing and equally share co-development costs for the three investigational molecules: domvanalimab, an Fc-silent anti-TIGIT antibody, etrumadenant, a dual adenosine A2a/A2b receptor antagonist, and zimberelimab, an anti-PD1 antibody.

Summary of Efficacy and Safety Observations from IA3:

- With more patients and longer follow up, both domvanalimab-containing arms continued to show meaningful differentiation compared to zimberelimab alone across multiple efficacy measures, including ORR and DoR.
- Since the last interim analysis, ORR for the doublet continued to increase and further separate from zimberelimab alone.
- Although early, the depth of response for the triplet remains encouraging; Arcus and Gilead will continue to monitor the triplet for potential differentiation in duration and depth of response vs. the doublet.
- At this interim analysis, Arcus performed its first assessment of DoR. While the data are still immature, at the time of IA3, Arcus observed a substantial improvement for the domvanalimab-containing arms compared to

zimberelimab alone.

- Zimberelimab alone continued to demonstrate activity consistent with that of marketed anti-PD-1 antibodies in the setting.
- No unexpected safety signals were observed; early safety data from this interim analysis showed a lower incidence of infusion reactions relative to published numbers from other anti-TIGIT plus anti-PD-(L)1 clinical studies.

Other Anti-TIGIT Updates:

- In May 2022, Arcus presented Phase 1 and preclinical data at the Annual Meeting of the American Association of Immunologists; the data demonstrated the potential of domvanalimab, as an Fc-silent antibody, to achieve anti-tumor effects and the incidence of pruritis, rash, maculopapular rash and infusion-related adverse events appear to be lower than Fc-enabled anti-TIGIT monoclonal antibodies. The poster can be found in the **publications** section of the Arcus website.

2022 Anti-TIGIT Milestones:

- Enrollment for ARC-7 remains on track to complete mid-2022; we expect to provide a data update in the second half of 2022.
- Arcus and Gilead plan to initiate STAR-121, in 4Q 2022, a Phase 3 registrational trial to evaluate the combination of domvanalimab plus zimberelimab and chemotherapy versus standard of care pembrolizumab with chemotherapy in first-line NSCLC PD-L1 all-comers.
- STAR-221, a pivotal Phase 3 study of a domvanalimab-based combination in upper gastrointestinal cancers, is currently in advanced stages of planning.
- Arcus and Gilead expect to initiate two signal-finding Phase 2 studies to further evaluate multiple domvanalimab-combinations, including triplet combinations with etrumadenant and quemliclustat, by year-end.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

Recent Etrumadenant Updates:

- Gilead announced the addition of etrumadenant plus Trodelvy® (sacituzumab govitecan-hziy) cohorts in the ongoing Phase 2 ARC-6 trial in castration-resistant prostate cancer.

2022 Etrumadenant Milestones:

- As discussed above, Arcus and Gilead expect to initiate a Phase 2 platform study to evaluate domvanalimab-based combinations, including with etrumadenant, this year.

- Data analysis from the randomized cohort of ARC-6 evaluating etrumadenant plus zimberelimab and docetaxel versus docetaxel in second-line metastatic castrate-resistant prostate cancer (CRPC) is anticipated in the second half of 2022 with a presentation of results expected in 2023.

Quemliclustat (small molecule CD73 inhibitor)

2022 Quemliclustat Milestones:

- Results from ARC-8, including an assessment of progression-free survival, are expected in the second half of 2022 with detailed results to be presented at a future medical congress.
- Additional clinical studies for quemliclustat are being planned with Gilead.

AB521 (HIF-2a inhibitor)

Recent AB521 Updates:

- Initial PK/PD data from the evaluation of AB521 in healthy human volunteers as well as preclinical data for AB521, alone and in combination with cabozantinib, were presented at the ESMO Targeted Anticancer Therapies Congress in March 2022. The early clinical data suggest that AB521 potentially has an improved clinical profile compared to that of the approved HIF-2a inhibitor.

2022 AB521 Milestones:

- A Phase 1/1b study to explore AB521 in clear-cell renal cell carcinoma, alone and in combination with other molecules, including those targeting the CD73-adenosine axis, is anticipated to be initiated in mid-2022. Data from the healthy volunteer study should enable Arcus to start dose escalation in patients at a biologically relevant dose level.

Discovery Programs:

- AB598 (Arcus' anti-CD39 antibody) continues to progress through preclinical development, and we expect to file an IND in the first half of 2023. Recent clinical data at AACR from a competitor antibody is supportive of Arcus' development plans for this molecule, in combination with other agents in our portfolio.
- Arcus anticipates selection of a development candidate for at least one other discovery program to occur this year, with potential for IND filing in 2023.

Financial Results for the First Quarter 2022

- Cash, cash equivalents and investments were $1,342.4 millionas of March 31, 2022, compared to $681.3 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, cash equivalents and marketable securities on-hand to be sufficient to fund operations into 2026.

- Revenues: Collaboration and license revenues were $18.0 million for the three months ended March 31, 2022, compared to $9.5 million for the same period in 2021. In the three months ended March 31, 2022, Arcus recognized $8.3 million in collaboration revenue related to Gilead's ongoing rights to access Arcus' research and development pipeline in accordance with the Gilead collaboration agreement, $7.9 million in license and development service revenues for all programs optioned by Gilead, based on estimates of progress made toward satisfying the related performance obligations, as well as $1.8 million related to the collaboration agreement with Taiho. In the three months ended March 31, 2021, Arcus recognized $7.7 million in other collaboration revenue related to Gilead's access to Arcus' research and development pipeline, as well as $1.8 million related to the Taiho collaboration agreement.
- R&D Expenses: Research and development expenses were $61.2 million for the three months ended March 31, 2022, compared to $66.4 million for the same period in 2021. The decrease was due to increased cost-sharing reimbursements from Gilead for its optioned programs and decreases in milestone expenses due to the timing of development milestones and the related payments, largely offset by an increase in costs incurred to support Arcus' expanded clinical and development activities. There was a $2.3 million increase in compensation costs related to non-cash stock-based compensation to approximately $8.5 million for the three months ended March 31, 2022 compared to the prior year period.
- G&A Expenses: General and administrative expenses were $24.0 million for the three months ended March 31, 2022, compared to $15.8 million for the same period in 2021. The increase was driven by the increased size and complexity of Arcus's clinical development organization associated with Arcus's expanding clinical pipeline and collaboration obligations. Arcus's growing employee base and 2022 stock awards drove increases in office facilities expense and employee compensation costs, including a $1.4 million increase in non-cash stock-based compensation to approximately $8.0 million for the three months ended March 31, 2022 compared to the prior year period.
- Net Loss: Net loss was $68.0 million for the three months ended March 31, 2022, compared to a net loss of $72.6 million for the same period in the prior year.

Arcus Ongoing and Announced Clinical Studies

Trial Name	Arms	Setting	Status	NCT No.
Lung Cancer				
ARC-7	zim vs. dom + zim vs. dom + etruma + zim	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Randomized Phase 2	NCT04262856
PACIFIC-8	dom + durva vs. durva	Curative-Intent Stage 3 NSCLC	Ongoing Registrational Phase 3	NCT05211895
ARC-10	dom + zim vs. zim vs. chemo	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Registrational Phase 3	NCT04736173
STAR-121	dom + zim + chemo vs pembro + chemo	1L NSCLC (PD-L1 all-comers)	Planned Registrational	TBD

			Phase 3	
EDGE-Lung	dom + zim + (quemli or etruma)	1L/2L NSCLC (lung cancer platform study)	In Planning Phase 2	TBD
Gastrointestinal Cancers				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	**NCT04660812**
ARC-21	dom + zim ± chemo	1L/2L Upper GI Malignancies	Ongoing Phase 2	**NCT05329766**
STAR-221	dom + zim + chemo vs. SOC	GI Malignancies	Planned Registrational Phase 3	TBD
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 (Adding sacituzumab govitecan (Trodelvy) 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 Volunteer	Ongoing	**NCT05117554**

Carbo/pem: carboplatin/pemetrexed; dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; quemli: quemliclustat; R/R: relapsed/refractory; SOC: standard of care; zim: zimberelimab 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 19.7%, with an additional $220 million investment.

Gilead and Arcus are co-developing and equally share global development costs for five clinical candidates, including domvanalimab, an Fc-silent anti-TIGIT antibody, etrumadenant, a dual adenosine A2a/A2b receptor antagonist, 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 most recently, HIF-2a. For more information about Arcus Biosciences' clinical and pre-clinical programs, please visit **www.arcusbio.com** or follow us on Twitter.

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, Arcus's expectation that its cash, cash equivalents and marketable securities on-hand are sufficient to fund operations into 2026, the potential of Arcus's molecules, upcoming data presentations, the projected achievement of clinical study milestones and their associated timing (including under the captions "2022 Anti-TIGIT Milestones," "2022 Etrumadenant Milestones," "2022 Quemliclustat Milestones," "2022 AB521 Milestones," and "Discovery Programs"), and additional clinical studies in planning or expected to be initiated this year 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed on May 9, 2022 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 and Comprehensive Loss
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	2021
Revenues:		
Other collaboration revenue	$ 10,066	$ 9,461
License and development service revenue	7,939	-
Total revenues	18,005	9,461
Operating expenses:		
Research and development	61,211	66,387
General and administrative	23,974	15,821
Total operating expenses	85,185	82,208
Loss from operations	(67,180)	(72,747)
Non-operating income (expense):		
Interest and other income, net	582	154
Effective interest on liability for sale of future royalties	(391)	-
Total non-operating income, net	191	154
Net loss before income taxes	(66,989)	(72,593)
Income tax expense	(1,004)	-
Net loss	(67,993)	(72,593)
Other comprehensive loss	(3,399)	(46)
Comprehensive loss	$ (71,392)	$ (72,639)
Net loss per share, basic and diluted	$ (0.96)	$ (1.08)
Weighted-average number of shares used to compute basic and diluted net loss per share	71,194,778	67,082,161

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

	March 31, 2022	December 31, 2021(1)
Cash, cash equivalents and investments in marketable securities	$ 1,342,370	$ 681,298
Total assets	1,543,427	1,591,898
Total liabilities	746,848	750,448
Total stockholders' equity	796,579	841,450

(1) Derived from the audited financial statements for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 23, 2022.

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