NEWS RELEASE

# Arcus Biosciences Reports Third Quarter 2022 Financial Results and Provides a Pipeline Update

11/2/2022

- Arcus and Gilead Sciences are pursuing a broad development strategy for their anti-TIGIT antibody domvanalimab in lung cancer, which now includes three ongoing registrational Phase 3 trials in multiple non-small cell lung cancer (NSCLC) settings; as part of this strategy, the companies have amended the study design of ARC-10, a registrational Phase 3 trial evaluating domvanalimab plus zimberelimab in first-line (1L) PD-L1≥50% NSCLC.
- Topline data disclosure for the ongoing ARC-7 trial in NSCLC is on track for this quarter with a planned presentation of the data at a medical conference in 2023.
- Arcus initiated ARC-20, a Phase 1/1b study of HIF-2a inhibitor AB521 in cancer patients; data from the healthy volunteer study enable Arcus to start dose escalation in patients at 25 mg once-daily, a pharmacologically active dose.
- With $1.2 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 third quarter ended September 30, 2022 and provided a pipeline update on its six clinical-stage molecules – targeting TIGIT, the adenosine axis (CD73 and A2a/A2b), HIF-2a and PD-1 – across multiple common cancers. As part of its pipeline update, the company is announcing a strategic protocol amendment to the ARC-10 registrational Phase 3 study following proactive discussions with the U.S. Food and Drug Administration (FDA). The new, amended ARC-10 study design will compare domvanalimab and zimberelimab to pembrolizumab, a

global standard-of-care (SOC) in PD-L1-high NSCLC, the target indication for ARC-10; the study will no longer include a chemotherapy arm.

“Arcus continues to execute on its strategy to be a leader in the TIGIT field and to advance our clinical pipeline, including our adenosine pathway modulators etrumadenant and quemliclustat,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “The optimization of our Phase 3 ARC-10 study design and the initiation of the fourth Phase 3 registrational study for domvanalimab position Arcus to leverage the full potential of domvanalimab. We continue to have strong conviction that domvanalimab plus zimberelimab has the potential to be a best-in-class anti-TIGIT / anti-PD-(L)1 regimen and to create a new standard-of-care in multiple settings. With $1.2 billion and a deep pipeline of six, soon to be eight, clinical-stage molecules, we are poised to be a leader in the development of innovative therapies for cancer patients in need.”

## ARC-10 Strategic Amendment

ARC-10 is a randomized Phase 3 study evaluating the efficacy of domvanalimab plus zimberelimab in 1L PD-L1≥50% locally advanced or metastatic NSCLC.

The strategic amendment revises the design to compare the combination of domvanalimab plus zimberelimab to SOC pembrolizumab, enabling an expanded geographic footprint for the trial. In addition, this amendment addresses the importance, both clinically and commercially, of using an accepted U.S. SOC as an active comparator for the trial, in the context of a potentially shifting U.S. regulatory landscape for oncology agents. The re-design of the ARC-10 study complements the ongoing STAR-121 study, comparing domvanalimab plus zimberelimab and chemotherapy versus SOC pembrolizumab plus chemotherapy, in 1L PD-L1 all-comer NSCLC. Together with the PACIFIC-8 study in Stage III NSCLC, these three registrational Phase 3 trials will establish the potential benefit of domvanalimab in a broad spectrum of NSCLC settings.

The key components of the protocol amendment for ARC-10, following proactive discussions with the FDA, are as follows:

- ARC-10 will now compare domvanalimab plus zimberelimab to SOC pembrolizumab for 1L PD-L1≥50% metastatic NSCLC and will no longer contain a chemotherapy arm.
    - The prior study design included three arms and compared domvanalimab plus zimberelimab to zimberelimab, and zimberelimab to chemotherapy.
    - The amendment significantly simplifies the study design and reduces the number of arms from three to two; the total trial size remains approximately the same (n=600).
    - Elimination of the chemotherapy arm and inclusion of the pembrolizumab arm as the active comparator will enable site activation in the U.S. and other countries that were previously excluded

from the study based on SOC.

- Based on FDA feedback on the primary endpoint for immuno-oncology therapies in 1L NSCLC, overall survival (OS) will be the primary endpoint.

### Additional Pipeline Highlights:

## Domvanalimab (Fc-silent anti-TIGIT monoclonal antibody)

### Domvanalimab Updates:

- In the third quarter, Arcus and Gilead initiated three new domvanalimab-based combination studies, including two registrational Phase 3 trials:
  - STAR-121, being operationalized by Gilead, is a registrational Phase 3 study to evaluate domvanalimab plus zimberelimab and chemotherapy versus SOC pembrolizumab plus chemotherapy in 1L PD-L1 all-comer NSCLC;
  - STAR-221 is a registrational Phase 3 study to evaluate domvanalimab plus zimberelimab and chemotherapy versus SOC nivolumab plus chemotherapy in 1L locally advanced unresectable or metastatic gastric, esophageal and gastro-esophageal junction adenocarcinomas;
  - ARC-21 is a Phase 2 study to evaluate domvanalimab plus zimberelimab-based combinations in upper gastrointestinal (GI) cancers.
- In the third quarter, Arcus completed enrollment of ARC-7, a 150-patient, randomized Phase 2 study evaluating the safety and efficacy of zimberelimab alone vs. domvanalimab plus zimberelimab vs. domvanalimab plus zimberelimab and etrumadenant in 1L PD-L1≥50% metastatic NSCLC.

### Upcoming Domvanalimab Milestones:

- The fourth interim analysis and topline data disclosure for ARC-7 is on track for this quarter, with a planned presentation of data at a medical conference in 2023.
- EDGE-Lung, a Phase 2 platform study to evaluate domvanalimab-, quemliclustat-, and zimberelimab-based combinations in advanced NSCLC, is expected to be initiated by the end of 2022.

## Etrumadenant (A2a/A2b adenosine receptor antagonist)

### Upcoming Etrumadenant Milestones:

- Data from the randomized cohort of ARC-6 evaluating etrumadenant plus zimberelimab and docetaxel versus docetaxel in second-line (2L) metastatic castrate-resistant prostate cancer (CRPC) are expected in-house by year-end, with a data presentation planned for 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 the first half of 2023.

## Quemliclustat (small-molecule CD73 inhibitor)

### Upcoming Quemliclustat Milestones:

- In the first half of 2023, Arcus expects PFS and OS data from all 90 patients in its ongoing ARC-8 trial evaluating quemliclustat plus chemotherapy with or without zimberelimab in first-line pancreatic cancer.
- EDGE-Lung, a Phase 2 platform study to evaluate domvanalimab-, quemliclustat-, and zimberelimab-based combinations in advanced NSCLC, is expected to be initiated by the end of 2022.
- Arcus expects to initiate one or more cohorts with quemliclustat-based combinations in GI cancers in the ongoing ARC-21 study.

## AB521 (HIF-2 a inhibitor)

### AB521 Update:

- In the third quarter, Arcus initiated ARC-20, a Phase 1/1b study exploring the safety and clinical activity of AB521 in cancer patients.
- In October, Arcus presented data at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium from the fourth cohort of ARC-14, a healthy volunteer study of AB521. The pharmacokinetic (PK) and pharmacodynamic (PD) data in healthy volunteers continue to support a potentially improved clinical profile compared to that of the approved HIF-2a inhibitor.

## Discovery Programs:

- Arcus remains on track to initiate a Phase 1 trial in cancer patients for AB598, its anti-CD39 antibody, in the first half of 2023.
- Arcus expects to initiate a Phase 1 trial in 2023 for its next small molecule program, AB801, a potent and highly selective Axl inhibitor. The early development plan is expected to focus on treatment-resistant tumor types, such as STK11-mutant NSCLC.
- Arcus expects to file an IND for its first candidate for the treatment of inflammatory disease in 2023. In October, as part of their research collaboration, Arcus received the third milestone payment of $5 million under its funding agreement with BVF Partners, L.P.

## Financial Results for the Third Quarter 2022

- Cash, cash equivalents and marketable securities: were $1,191.9 millionas of September 30, 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: Revenues were $33.6 million for the three months ended September 30, 2022, compared to $9.5 million for the same period in 2021. In the three months ended September 30, 2022, Arcus recognized $23.7 million in license and development service revenues for all programs optioned by Gilead, including $8.9 million in revenues due to changes in the total estimated effort to be incurred in the future to satisfy the performance obligations, primarily driven by zimberelimab. Arcus further recognized $8.3 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, as well as $1.5 million related to the collaboration agreement with Taiho. In the three months ended September 30, 2021, Arcus recognized $7.7 million in other collaboration revenue related to Gilead's access to Arcus's research and development pipeline, as well as $1.8 million related to the Taiho collaboration agreement. Revenues were $78.3 million for the nine months ended September 30, 2022, compared to $28.4 million for the same period in 2021.
- R&D Expenses: Research and development expenses were $76.7 million for the three months ended September 30, 2022, compared to $71.3 million for the same period in 2021. Arcus's expanding clinical and development activities for domvanalimab and zimberelimab in combination studies drove increases in manufacturing and clinical costs. Arcus's growing employee base and 2022 stock awards drove an $8.5 million increase in employee compensation costs, which includes a $0.2 million increase in non-cash stock-based compensation. The above increases in research and development costs were mostly offset by increased cost-sharing reimbursements compared to the same quarter in the prior year. The increase in cost-sharing reimbursements was driven by the four programs optioned by Gilead in the current quarter, compared to a single program in the same quarter of the prior year. Research and development expenses were $207.8 million for the nine months ended September 30, 2022, compared to $206.4 million for the same period in 2021.
- G&A Expenses: General and administrative expenses were $26.3 million for the three months ended September 30, 2022, compared to $16.3 million for the same period in 2021. The increase was driven by the increased administrative costs to support the growing 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 a $3.7 million increase in employee compensation costs, which includes a $1.6 million increase in non-cash stock-based compensation, as well as increases in office facilities and consulting expenses. General and administrative expenses were $76.1 million for the nine months ended September 30, 2022, compared to $49.0 million for the same period in 2021.
- Net Loss: Net loss was $64.9 million for the three months ended September 30, 2022, compared to a net loss

of $78.0 million for the same period in the prior year. Net loss was $199.5 million for the nine months ended September 30, 2022, compared to a net loss of $226.5 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. etruma + dom + zim | 1L NSCLC (PD-L1 ≥ 50%) | Ongoing Randomized Phase 2 | **NCT04262856** |
| PACIFIC-8 (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 (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) | Initiating Phase 2 | TBD |
| Velocity-Lung (GILD) | dom +/- zim +/- etruma +/- sacituzumab govitecan (Trodelvy®) or other combos | 1L/2L NSCLC (lung cancer platform study) | Initiating 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. nivo + chemo | 1L Gastric, Gastroesophageal Junction (GEJ), and Esophageal Adenocarcinoma (EAC) | Planned 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 (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 Volunteers | Ongoing | **NCT05117554** |
| ARC-20 | AB521 | Cancer Patients / ccRCC | Planned 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.

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, 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.

## 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 "Discovery Programs"), and additional clinical studies in planning or expected to be initiated 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 September 30, 2022, filed on November 2, 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Revenues: | | | | |
| License and development service revenue | $ 23,742 | $ - | $ 48,374 | $ - |
| Other collaboration revenue | 9,839 | 9,461 | 29,971 | 28,383 |
| Total revenues | 33,581 | 9,461 | 78,345 | 28,383 |
| Operating expenses: | | | | |
| Research and development | 76,684 | 71,254 | 207,800 | 206,412 |
| General and administrative | 26,294 | 16,343 | 76,104 | 48,990 |
| Total operating expenses | 102,978 | 87,597 | 283,904 | 255,402 |
| Loss from operations | (69,397) | (78,136) | (205,559) | (227,019) |
| Non-operating income (expense): | | | | |
| Interest and other income, net | 5,013 | 161 | 8,456 | 481 |
| Effective interest on liability for sale of future royalties | (535) | - | (1,437) | - |
| Total non-operating income, net | 4,478 | 161 | 7,019 | 481 |
| Net loss before income taxes | (64,919) | (77,975) | (198,540) | (226,538) |
| Income tax expense | - | - | (1,004) | - |
| Net loss | (64,919) | (77,975) | (199,544) | (226,538) |
| Other comprehensive loss | (2,557) | (46) | (8,540) | (136) |
| Comprehensive loss | $ (67,476) | $ (78,021) | $ (208,084) | $ (226,674) |
| Net loss per share, basic and diluted | $ (0.90) | $ (1.11) | $ (2.78) | $ (3.28) |
| Weighted-average number of shares used to compute basic and diluted net loss per share | 72,236,283 | 70,110,138 | 71,752,246 | 68,990,290 |

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

| | September 30, 2022 | December 31, 2021(1) |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 1,191,920 | $ 681,298 |
| Total assets | 1,393,822 | 1,591,898 |
| Total liabilities | 695,121 | 750,448 |
| Total stockholders' equity | 698,701 | 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.


## Investor Inquiries:

Pia Banerjee

Head of Investor Relations & Strategy

(617) 459-2006

**pbanerjee@arcusbio.com**

## Media Inquiries:

Holli Kolkey

VP of Corporate Communications

(650) 922-1269

**hkolkey@arcusbio.com**


Source: Arcus Biosciences