NEWS RELEASE

# Arcus Biosciences Reports Third Quarter 2021 Financial Results and Provides an Update on our anti-TIGIT Domvanalimab

11/8/2021

- Both domvanalimab-containing arms demonstrated differentiated clinical activity compared to that of zimberelimab alone in a second interim analysis of ARC-7, our randomized Phase 2 study in first-line metastatic non-small cell lung cancer (NSCLC)
- Gilead Sciences has initiated its opt-in review process for our anti-TIGIT program
    - If the option is exercised and closed, Arcus would receive a $275 million opt-in payment, and the parties would share equally R&D expenses related to the anti-TIGIT program
    - A decision is expected prior to the end of 2021
- Updated data from ARC-8, a Phase 1 study of quemliclustat, our small molecule anti-CD73 inhibitor for pancreatic cancer, is planned for fall 2021
- Arcus ended the quarter with $743 million of cash and investments and funding through at least 2023

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, 2021 and provided an update on the ARC-7 study of domvanalimab. Gilead Sciences has initiated its opt-in review process to potentially obtain rights to the Arcus anti-TIGIT program. If the option is exercised and closed, Gilead would obtain rights to both domvanalimab and AB308, a second and differentiated anti-TIGIT antibody in the Arcus portfolio. A decision is expected prior to the end of 2021.

“The initiation of Gilead’s opt-in review process for our anti-TIGIT program is an important step towards our shared commitment to develop differentiated combination therapies for people with cancer,” said Terry Rosen, Ph.D., Chief Executive Officer of Arcus. “We expect to continue our strong momentum of significant program advancement and milestone achievement starting with an update this fall from our Phase 1 study of quemliclustat, our first-in-class small molecule CD73 inhibitor, in development for pancreatic cancer, an area of enormous unmet need. Quemliclustat is a central component of our late-stage development strategy for 2022 and beyond.”

## Corporate & Partnership Updates

- Gilead initiated the opt-in review process for our anti-TIGIT program. A decision is expected prior to the end of 2021. If Gilead exercises its option, and subject to receipt of applicable anti-trust approvals:
    - Arcus would receive a $275 million opt-in payment, and the parties would co-develop and share equally the global development costs related to the anti-TIGIT program.
    - Gilead would obtain rights to both domvanalimab, our Fc-silent anti-TIGIT antibody currently being evaluated in Phase 2 and Phase 3 studies, and AB308, our Fc-enabled anti-TIGIT antibody currently in a Phase 1 study in advanced malignancies.
    - If approved, Arcus and Gilead would co-commercialize and equally share profits and losses to both anti-TIGIT antibodies in the United States. Gilead would receive exclusive rights outside the U.S., subject to any rights of Arcus’s existing partners, and Gilead would pay to Arcus tiered royalties ranging from the high teens to low twenties.
- Our collaboration partner Taiho initiated a Phase 1 platform study evaluating zimberelimab (our anti-PD1 antibody) with Taiho’s intra-portfolio combinations targeting oncology indications. The TARP (Taiho-Arcus Platform) study is currently enrolling. Further details can be found at **https://clinicaltrials.gov** Trial Identifier: NCT04999761.
- Zimberelimab was approved in China as a second-line treatment for recurrent/refractory classical Hodgkin lymphoma (CHL); Gloria Biosciences holds all rights to zimberelimab in China and conducts its development of zimberelimab independent of Arcus’s activities.

## Anti-TIGIT program

## Recent Highlights

- Arcus conducted a second interim analysis (IA2) for ARC-7, ouropen-label randomized Phase 2 study evaluating the safety and efficacy of domvanalimab plus zimberelimab vs. zimberelimab alone vs. domvanalimab plus zimberelimab and etrumadenant (dual adenosine A2a/A2b receptor antagonist) as a first-line treatment for PD-L1 ≥ 50% and EGFR/ALK wild-type, metastatic NSCLC. 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. The timing of this interim analysis was pre-specified in the protocol to occur when a certain number of patients were randomized and had at least two disease evaluations.

## Summary of Efficacy Observations from IA2:

- Both domvanalimab-containing arms demonstrated differentiated clinical activity compared to that of zimberelimab alone.
    - Zimberelimab alone continued to demonstrate activity similar to that of other marketed anti-PD-1 antibodies in the setting.
    - As expected with immunotherapy treatments, continued deepening of response and greater tumor shrinkage were observed in patients with longer follow-up in both domvanalimab-containing arms.
        - Since the previous interim analysis, the doublet continued to show encouraging activity relative to the monotherapy, and the triplet continued to numerically outperform the doublet.
    - As of the data cut-off date for this interim analysis, data for progression-free survival (PFS) was immature but indicated that fewer events of progression or death had occurred in the domvanalimab-containing arms compared to zimberelimab alone.

## Summary of Safety Observations from IA2:

- No unexpected safety signals were observed; the current safety profile for each molecule in the study appeared to be consistent with known and published immune checkpoint inhibitors in this setting.
- 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.
- Arcus initiated enrollment of five expansion cohorts in the Phase 1b portion of the ARC-12 study evaluating AB308 plus zimberelimab in advanced malignancies. This study is designed to evaluate the safety, tolerability, pharmacokinetic, pharmacodynamic and clinical activity of AB308 plus zimberelimab in tumor types believed to be potentially responsive to anti-TIGIT antibodies.

## Upcoming anti-TIGIT Milestones:

- ARC-7 is expected to be fully enrolled by mid-2022, and we anticipate a data presentation later in 2022, which will include progression-free survival data.
- ARC-10, an ongoing registrational Phase 3 study in first-line, locally advanced or metastatic PD-L1≥50% NSCLC, continues to enroll and, if positive, is intended to support the potential approvals of both zimberelimab monotherapy and domvanalimab plus zimberelimab.
- AstraZeneca and Arcus remain on track to initiate the PACIFIC-8 registrational Phase 3 study to evaluate

domvanalimab plus durvalumab, an anti-PD-L1 antibody, in unresectable Stage 3 NSCLC with curative intent, where durvalumab is standard of care, by the end of 2021.
- We are planning several additional clinical studies of domvanalimab-based combinations, including two additional Phase 3 studies anticipated to start in mid-2022.

## Quemliclustat (small molecule anti-CD73 inhibitor)

## Upcoming Milestones:

- An update on ARC-8, our Phase I study of quemliclustat plus zimberelimab and gemcitabine/nab-paclitaxel in first-line metastatic pancreatic ductal adenocarcinoma (PDAC), is planned for this fall. This update includes data on approximately 30 patients treated at the 100mg and 125mg dose of quemliclustat.
- We expect the randomized portion of ARC-8 to complete enrollment by the end of this month. This 90-patient cohort is evaluating quemliclustat plus zimberelimab and gemcitabine/nab-paclitaxel vs. quemliclustat plus gemcitabine/nab-paclitaxel to determine whether zimberelimab adds clinical benefit to the combination.
- We anticipate landmark six-month PFS data from the randomized portion of ARC-8 in mid-2022. These results will inform the design of our planned Phase 3 study with the goal of starting this first registrational study for quemliclustat in 2022.

## Etrumadenant (A2a/A2b adenosine receptor antagonist)

## Upcoming Milestones:

- ARC-4, our randomized Phase 1b study in EGFR+ NSCLC: we expect initial randomized data, including overall response rates and PFS, to be presented in 1H22. ARC-4 is evaluating etrumadenant plus zimberelimab and chemotherapy vs. zimberelimab plus chemotherapy in EGFRmut tyrosine kinase inhibitor (TKI)-relapsed and refractory NSCLC.
- ARC-6, our Phase 1b/2 platform study in metastatic castration-resistant prostate cancer: we anticipate initial results in 2022 from the randomized cohort that is evaluating docetaxel versus docetaxel plus etrumadenant and zimberelimab.

## Discovery Programs:

## Upcoming Milestones:

- AB308 (Fc-enabled anti-TIGIT antibody) poster presentation at the 2021 Society for Immunotherapy of Cancer's (SITC) Annual Meeting, November 10-14, 2021.
    - Poster #258, Title: AB308 is an Anti-TIGIT Antibody That Enhances Immune Activation and Anti-tumor Immunity Alone and in Combination with Other I-O Therapeutic Agents.

- AB521 (HIF-2α inhibitor): we expect to initiate Phase 1 clinical development in the fourth quarter of 2021. This first study is in healthy volunteers and is designed to expeditiously characterize the pharmacokinetic and safety profile of AB521 and to identify the starting dose for the planned Phase 1/1b study in oncology patients.

## Financial Results for the Third Quarter 2021

- Cash, cash equivalents and investments were $743.4 millionas of September 30, 2021, compared to $735.1 million as of December 31, 2020. The increase was primarily due to gross proceeds of $220.4 million received upon the closing of the private placement of common stock under the Amended and Restated Stock Purchase Agreement with Gilead in February 2021, partially offset by cash utilized for our operations. We expect cash, cash equivalents and marketable securities on hand to be sufficient to fund operations at least through 2023.
- Revenues: Collaboration and license revenues were $9.5 million for the three months ended September 30, 2021, compared to $64.5 million for the same period in 2020. In the three months ended September 30, 2021, we recognized $7.7 million in collaboration revenue related to Gilead's ongoing rights to access our research and development pipeline in accordance with the Gilead collaboration agreement, as well as $1.8 million related to the Taiho collaboration agreement. In the three months ended September 30, 2020, we recognized $55.1 million in revenue related to Gilead's license to zimberelimab and $7.7 million in collaboration revenue related to their access to our research and development pipeline, as well as $1.8 million related to the Taiho collaboration agreement. Collaboration and license revenues were $28.4 million for the nine months ended September 30, 2021, compared to $68.0 million for the same period in 2020.
- R&D Expenses: Research and development expenses were $71.3 million for the three months ended September 30, 2021, compared to $51.8 million for the same period in 2020. The increase was primarily driven by costs incurred to support our expanded clinical and development activities including increased compensation costs related to a larger employee base, increased clinical trial costs, and increased early-stage research costs. Approximately $4.9 million of the increase in compensation costs is related to non-cash stock-based compensation. The overall increase in research and development expenses is partially offset by a decrease in milestone expenses incurred. Research and development expenses were $206.4 million for the nine months ended September 30, 2021, compared to $110.6 million for the same period in 2020.
- G&A Expenses: General and administrative expenses were $16.3 million for the three months ended September 30, 2021, compared to $11.2 million for the same period in 2020. The increase was driven by the increased complexity of supporting our expanding clinical pipeline and collaboration obligations, as well as compliance costs associated with our growth. Our growing employee base and 2021 stock awards drove an increase in employee compensation costs, including approximately $3.7 million of increased non-cash stock-based compensation. The overall increase was partially offset by decreases in legal, accounting and consulting expenses due to costs related to the transaction with Gilead and other corporate development activities

incurred in 2020. General and administrative expenses were $49.0 million for the nine months ended September 30, 2021, compared to $29.6 million for the same period in 2020.

- Net Loss: Net loss was $78.0 million for the three months ended September 30, 2021, compared to net income of $1.8 million for the same period in the prior year. Net loss was $226.5 million for the nine months ended September 30, 2021, compared to $71.0 million for the same period in 2020.

## Arcus Clinical Study Overview

| Trial Name | Arms | Setting | Status | NCT No. |
|---|---|---|---|---|
| ARC-4 | etruma + zim + carbo/pem vs. zim + carbo/pem | TKI R/R EGFRmut NSCLC | Ongoing Randomized Phase 1/2 | NCT03846310 |
| ARC-6 | etruma + zim + SOC vs. SOC | 2L/3L CRPC | Ongoing Randomized Phase 2 | NCT04381832 |
| ARC-7 | zim vs. zim + dom vs. zim + dom + etruma | 1L NSCLC (PD-L1 ≥ 50%) | Ongoing Randomized Phase 2 | NCT04262856 |
| ARC-8 | quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac | 1L PDAC | Ongoing Randomized Phase 1/1b | NCT04104672 |
| ARC-9 | etruma + zim + mFOLFOX vs. SOC | 2L/3L/3L+ CRC | Ongoing Randomized Phase 2 | NCT04660812 |
| ARC-10 | chemo vs. zim mono vs. zim + dom | 1L NSCLC (PD-L1 ≥ 50%) | Ongoing Registrational | NCT04736173 |
| ARC-12 | AB308 + zim | Advanced Malignancies | Ongoing Phase 1/1b | NCT04772989 |
| ARC-14 | AB521 | Healthy Volunteer | Planned Phase 1 | NA |
| PACIFIC-8 | durva ± dom | Curative-Intent Stage 3 NSCLC | Planned Registrational | NA |

Carbo/pem: carboplatin/pemetrexed; dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; quemli: quemliclustat; SOC: standard of care; zim: zimberelimab CRC: colorectal cancer; CRPC: castrate-resistant prostate cancer; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma

## About domvanalimab and AB308

Domvanalimab, Arcus's most advanced anti-TIGIT candidate, is an Fc-silent investigational monoclonal antibody that binds to TIGIT, a protein receptor on immune cells that acts as a brake on the immune response. Cancer cells can exploit TIGIT to avoid detection by the immune system. Domvanalimab binds to TIGIT to free up immune activating pathways and activate immune cells to attack and kill cancer cells.

Treatment with domvanalimab, an Fc-silent antibody, has not been associated with the depletion of peripheral regulatory T-cells. We believe this may result in fewer infusion reactions relative to what has been reported for other anti-TIGIT-containing regimens.

Arcus is developing a second anti-TIGIT candidate, AB308, an Fc-enabled investigational monoclonal antibody. AB308 is currently in a Phase I study for advanced malignancies.

## 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. For clinical programs in existence at the date of the agreement, Gilead's opt-in payment ranges from $200 million to $275 million per program. For all other 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 prescribed 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 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.

## 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 biology 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) and most recently, HIF-2alfa. 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, statements regarding the potential exercise, timing and receipt of payments upon an exercise by Gilead of its option to our anti-TIGIT program, upcoming milestone and associated timing for our programs, including those statements under the captions "Upcoming Milestones" above and expected enrolment in the studies and cohorts described herein, and our expectation that our cash, cash equivalents and marketable securities on-hand will be sufficient to fund operations through at least 2023, 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 our 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: the ability to

obtain regulatory approval for any exercise by Gilead of its option; risks associated with preliminary and interim data; the unexpected emergence of adverse events or other undesirable side effects; the inherent uncertainty associated with the COVID-19 pandemic, including the duration and/or severity of the pandemic and actions by government authorities to contain or slow the spread of the virus; the inherent uncertainty associated with pharmaceutical product development and clinical trials; delays in our clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; our dependence on our collaboration with Gilead for the successful development and commercialization of our investigational products; and changes in the competitive landscape for our programs. Risks and uncertainties facing us are described more fully in our quarterly report on Form 10-Q for the quarter ended September 30, 2021 filed on November 8, 2021 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. We disclaim any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.



Source: Arcus Biosciences

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, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenues: | | | | |
| License revenue | $ - | $ 55,096 | $ - | $ 55,096 |
| Collaboration revenue | 9,461 | 9,434 | 28,383 | 12,934 |
| Total revenues | 9,461 | 64,530 | 28,383 | 68,030 |
| Operating expenses: | | | | |
| Research and development | 71,254 | 51,801 | 206,412 | 110,636 |
| General and administrative | 16,343 | 11,177 | 48,990 | 29,617 |
| Total operating expenses | 87,597 | 62,978 | 255,402 | 140,253 |
| Income (loss) from operations | (78,136) | 1,552 | (227,019) | (72,223) |
| Non-operating income (expense): | | | | |
| Interest and other income, net | 161 | 270 | 481 | 1,218 |
| Gain on deemed sale from equity method investee | - | - | - | 613 |
| Share of loss from equity method investee | - | - | - | (613) |
| Total non-operating income, net | 161 | 270 | 481 | 1,218 |
| Net loss | (77,975) | 1,822 | (226,538) | (71,005) |
| Other comprehensive income (loss) | (46) | (63) | (136) | 17 |
| Comprehensive loss | $ (78,021) | $ 1,759 | $ (226,674) | $ (70,988) |
| Net income (loss) per share, basic | $ (1.11) | $ 0.03 | $ (3.28) | $ (1.37) |
| Weighted-average number of shares used to compute basic net income (loss) per share | 70,110,138 | 62,599,193 | 68,990,290 | 51,852,247 |
| Net income (loss) per share, diluted | $ (1.11) | $ 0.03 | $ (3.28) | $ (1.37) |
| Weighted-average number of shares used to compute diluted net income (loss) per share | 70,110,138 | 65,145,707 | 68,990,290 | 51,852,247 |

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

| | September 30, 2021 | December 31, 2020(1) |
|---|---|---|
| Cash, cash equivalents and investments in marketable securities | $ 743,372 | $ 735,086 |
| Total assets | 839,290 | 772,292 |
| Total liabilities | 296,683 | 269,988 |
| Total stockholders' equity | 542,607 | 502,304 |

(1) Derived from the audited financial statements for the year ended December 31, 2020, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2021.

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Source: Arcus Biosciences, Inc.