



NEWS RELEASE

Arcus Biosciences Reports First Quarter 2021 Financial Results and Provides Operational Highlights

5/5/2021

- Continued to advance our portfolio of anti-TIGIT antibodies: On track for the ARC-7 interim analysis for domvanalimab in 2Q21, and the first patient was dosed with AB308 in combination with zimberelimab
- Presented promising PFS and OS data for etrumadenant in the $\geq 3L$ metastatic colorectal cancer setting at AACR
- Initiated the randomized portion of our ARC-8 study evaluating AB680, our first-in-class small molecule CD73 inhibitor, in pancreatic cancer following rapid completion of enrollment of the dose-expansion portion of the study
- Presented preclinical data on a novel series of HIF-2 α inhibitors at AACR, including data on AB521, and remain on track to initiate clinical development for this program in 2H21
- Ended the quarter with \$885 million of cash and investments

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), an oncology-focused biopharmaceutical company working to create best-in-class cancer therapies, today reported financial results for the first quarter ended March 31, 2021 and provided operational highlights.

"Our ongoing clinical trials include six randomized studies with several that are expected to provide meaningful readouts over the next 12 months," said Terry Rosen, Ph.D., CEO. "We expect the next milestone in our anti-TIGIT program, the ARC-7 interim analysis, later this quarter. We also continue to generate substantial clinical evidence to support our first-in-class therapies targeting the ATP-adenosine axis having recently presented data from ARC-3 which showed a doubling of progression-free survival and overall survival for etrumadenant and chemotherapy in

late-line colorectal cancer compared to those reported for current standard-of-care therapies, and promising results for AB680 in first-line pancreatic cancer. We will present initial data from ARC-6, evaluating etrumadenant plus zimberelimab and chemotherapy in metastatic castrate-resistant prostate cancer, at the upcoming ASCO Annual Meeting.”

Anti-TIGIT Program

Domvanalimab (FcR-silent anti-TIGIT antibody).

Recent Highlights:

- First patient dosed in ARC-10, Arcus’s first global registrational trial , evaluating domvanalimab + zimberelimab vs. zimberelimab vs. chemotherapy in first-line PD-L1 \geq 50%, locally advanced or metastatic non-small cell lung cancer (NSCLC). This study is designed to seek approval for both zimberelimab monotherapy as well as domvanalimab + zimberelimab in this setting. Gilead and Arcus have been actively collaborating to define a broad clinical development program for domvanalimab, and Arcus expects to announce other registrational trials for domvanalimab later this year.

Upcoming Milestones:

- Results from the interim analysis for ARC-7 , a randomized, three-arm Phase 2 trial evaluating domvanalimab + zimberelimab vs. zimberelimab vs. domvanalimab + zimberelimab + etrumadenant in first-line PD-L1 \geq 50%, locally advanced or metastatic NSCLC are expected in the second quarter of 2021. A 50% or greater ORR for the zimberelimab + domvanalimab combination and clear separation from the zimberelimab arm would be considered a positive outcome for the interim analysis by Arcus and Gilead and could inform a potential opt-in decision. We expect to present the data from this analysis at a medical conference in the second half of 2021.

AB308 (FcR-enabled anti-TIGIT antibody).

- First patient dosed in the ARC-12 study evaluating AB308 in combination with zimberelimab in the second quarter of 2021. By initially evaluating AB308 in combination with an anti-PD1 antibody, this study is designed to efficiently establish the safety and optimal dose of AB308 + zimberelimab to facilitate advancement into a late-stage trial. We plan to evaluate AB308 in settings, such as certain hematological malignancies, where the depletion of TIGIT-bearing cancer cells could be beneficial.

AB680 (CD73 inhibitor).

Recent Highlights:

- Completed enrollment of the dose-expansion portion and initiated the randomized portion of ARC-8 , a Phase 1/1b study evaluating AB680 + zimberelimab + gemcitabine/nab-paclitaxel (G/NP) in first-line metastatic pancreatic cancer. The randomized portion includes a control arm of AB680 + G/NP to help inform the design of a potential registrational trial. Enrollment in ARC-8 has proceeded very quickly, and if data continue to look promising, we anticipate discussing these data and the path to registration with health authorities in the second half of 2021.
- Evaluation of the oral formulation of AB680 in healthy volunteers demonstrated the ability to achieve the desired circulating drug levels. Having an oral formulation of AB680 provides additional dosing flexibility and the ability to combine AB680 with other orally administered therapies.
- Opened a second cohort evaluating the synergistic potential of AB680 and etrumadenant. This cohort is part of our recently initiated ARC-9 metastatic colorectal cancer (mCRC) platform study. The first cohort evaluating AB680 + etrumadenant, described last quarter, is part of our ongoing ARC-6 metastatic castrate-resistant prostate cancer (mCRPC) platform study.

Upcoming Milestones:

- Presentation of additional data from ARC-8 , including more mature data from the dose-escalation and initial data from the dose-expansion portions of the study, at a medical conference in the second half of 2021.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

Recent Highlights:

- Presented very encouraging results for ARC-3, a Phase 1/1b trial evaluating etrumadenant in combination with mFOLFOX, at the 2021 AACR Annual Meeting. The etrumadenant combination demonstrated a 4.2 month median progression-free survival and 13.6 month median overall survival, approximately double those reported for current standard of care therapies in the $\geq 3L$ mCRC setting. These are very encouraging data in heavily pre-treated patients. In addition, the etrumadenant + mFOLFOX combination was well tolerated, and etrumadenant did not appear to add significant toxicity to that expected for mFOLFOX-6. ARC-9, our ongoing randomized Phase 1b/2 platform study evaluating etrumadenant in combination with other agents in $\geq 2L$ mCRC, builds on the encouraging data from the ARC-3 study.

Upcoming Milestones:

- Presentation of initial data from the ARC-6 study in a poster at the 2021 ASCO Annual Meeting, June 4-8th , titled: "ARC-6: A Phase 1b/2, Open-Label, Randomized Platform Study to Evaluate Efficacy and Safety of Etrumadenant (AB928)-Based Treatment Combinations in Patients with mCRPC."

- Initial data from the Stage 2 randomized portion of this study are expected to be presented in early 2022.
- Presentation of initial randomized data from ARC-4 , an ongoing study evaluating etrumadenant + zimberelimab + chemotherapy vs. zimberelimab + chemotherapy in EGFRmut tyrosine kinase inhibitor (TKI)-relapsed and refractory NSCLC, expected at a medical conference in the second half of 2021.

HIF-2α inhibitor Program

- Initiation of clinical development for our HIF-2α inhibitor is anticipated to occur in the second half of 2021. At the 2021 AACR Annual Meeting, we presented details of our Hypoxia-Inducible Factor 2α (HIF-2α) research program, including the design of a novel series of HIF-2α inhibitors, which has resulted in the identification of molecules such as AB521, with excellent potency, selectivity, biological activity and pharmacokinetic properties suitable for further development.

Financial Results for the First Quarter 2021 Ended March 31, 2021

- Cash, cash equivalents and investments were \$884.9 million as of March 31, 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 March 31, 2021, compared to \$1.8 million for the same period in 2020. In the three months ended March 31, 2021, we recognized \$7.7 million in collaboration revenues 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 under the Taiho Agreement. In the three months ended March 31, 2020, we recognized \$1.8 million under the Taiho Agreement.
- R&D Expenses: Research and development expenses were \$66.4 million for the three months ended March 31, 2021, compared to \$23.1 million for the same period in 2020. The increase was primarily due to \$15.0 million of sublicense and milestone expense in the 2021 period as compared to no amounts in the 2020 period. Increases in employee compensation costs, approximately \$4.4 million of which consists of non-cash stock-based compensation, also contributed to the overall expense increase and were driven by increasing headcount and 2021 stock awards. Manufacturing and clinical costs increased as well due to the increased number of clinical programs and studies compared to the same quarter in the prior year. Office and facilities expense increased as we continued to grow. The overall increase in research and development expenses is partially offset by a \$4.9 million reimbursement by Gilead of certain applicable costs of developing zimberelimab, including \$4.0 million reimbursement related to milestone expense incurred.

- G&A Expenses: General and administrative expenses were \$15.8 million for the three months ended March 31, 2021, compared to \$7.0 million for the same period in 2020. The increase in expense was due to increases in employee compensation, approximately \$4.9 million of which consists of non-cash stock-based compensation, driven by increasing headcount and 2021 stock awards. Additional increases in finance and legal expenses were largely driven by costs incurred to support our growth and ongoing compliance with public company requirements, and we incurred additional facilities expense due to our expanding headcount and office space.
- Net Loss: Net loss was \$72.6 million for the three months ended March 31, 2021, compared to a net loss of \$27.8 million for the same period in the prior year. The increase in net loss as compared to the same period in the prior year was primarily attributable to our expanding operations including advancements in our clinical pipeline and related milestone payments, partially offset by increased revenues due to the Gilead Collaboration Agreement.

Arcus Clinical Study Overview

Trial Name	Arms	Setting	Status	NCT No.
ARC-3	Etruma + mFOLFOX	CRC	Initial Study	NCT03720678
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	AB680 + Zim + Gem/NP vs. AB680 + Gem/NP	1L PDAC	Ongoing Randomized Phase 1/1b	NCT04104672
ARC-9	Etruma + Zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Initiated Randomized Phase 2	NCT04660812
ARC-10	Chemo vs. Zim mono vs. Zim + Dom	1L NSCLC (PD-L1 ≥ 50%)	Initiated Registrational	NCT04736173
ARC-12	AB308 + Zim	Advanced Malignancies	Initiated Phase 1/1b	NCT04772989
PACIFIC-8	Durva ± Dom	Curative-Intent Stage 3 NSCLC	Expected initiation 2H21 Registrational	NA

CRC: colorectal cancer, NSCLC: non-small cell lung cancer, CRPC: castrate-resistant prostate cancer, PDAC: pancreatic ductal adenocarcinoma, Durva: durvalumab

About Arcus Biosciences

Arcus Biosciences is an oncology-focused biopharmaceutical company leveraging its deep cross-disciplinary expertise to discover highly differentiated therapies and to develop a broad portfolio of novel combinations addressing significant unmet needs. Arcus currently has five molecules in clinical development: **Etrumadenant (AB928)**, the first dual A2a/A2b adenosine receptor antagonist to enter the clinic, is being evaluated in multiple Phase 2 and 1b studies across different indications, including prostate, colorectal, non-small cell lung, and pancreatic cancers. **AB680**, the first small-molecule CD73 inhibitor to enter the clinic, is in Phase 1/1b development for first-line treatment of metastatic pancreatic cancer in combination with zimberelimab and gemcitabine/nab-paclitaxel. **Domvanalimab (AB154)**, an anti-TIGIT monoclonal antibody and new potential

immuno-oncology backbone therapy, is in a three-arm randomized Phase 2 study for first-line treatment of PD-L1 \geq 50% locally advanced or metastatic non-small cell lung cancer (NSCLC) evaluating zimberelimab monotherapy, domvanalimab + zimberelimab and domvanalimab + etrumadenant + zimberelimab. In addition, domvanalimab has advanced into ARC-10, Arcus's "two in one trial" to support the potential approvals of both zimberelimab and zimberelimab + domvanalimab and is expected to advance into a registrational study, in collaboration with AstraZeneca, evaluating the curative-intent stage 3 NSCLC setting later this year. **AB308**, an anti-TIGIT antibody that is FcR-enabled, advanced into clinical development to investigate additional indications, with a focus on hematological malignancies. **Zimberelimab (AB122)**, Arcus's anti-PD-1 monoclonal antibody, was in-licensed to enable the development of Arcus's combination regimens and is being evaluated in various combinations across the portfolio. For more information about Arcus Biosciences, please visit www.arcusbio.com.

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 expectations for meaningful readouts and ability to generate substantial clinical evidence as set forth in Dr. Rosen's quote, the potential for the ARC-7 interim analysis to inform a potential opt-in decision by Gilead, Arcus's anticipated milestones and associated timelines described herein and Arcus's expectation that its 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, uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or implied. Factors that could cause or contribute to such differences include, but are not limited to: the inherent uncertainty associated with the COVID-19 pandemic, including the duration and/or severity of the outbreak 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; our dependence on our collaboration with Gilead for the successful development and commercialization of our investigational products; 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; the unexpected emergence of adverse events or other undesirable side effects; risks associated with preliminary and interim data; and changes in the competitive landscape for our programs. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended March 31, 2021 filed on May 5, 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. Arcus disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

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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 March 31,	
	2021	2020
Revenues:		
Collaboration revenue	\$ 9,461	\$ 1,750
Total collaboration and license revenues	9,461	1,750
Operating expenses:		
Research and development	66,387	23,142
General and administrative	15,821	7,008
Total operating expenses	82,208	30,150
Loss from operations	(72,747)	(28,400)
Non-operating income (expense):		
Interest and other income, net	154	647
Gain on deemed sale from equity method investee	-	482
Share of loss from equity method investee	-	(482)
Total non-operating income, net	154	647
Net loss	(72,593)	(27,753)
Other comprehensive income (loss)	(46)	224
Comprehensive loss	\$ (72,639)	\$ (27,529)
Net loss per share, basic and diluted	\$ (1.08)	\$ (0.63)
Weighted-average number of shares used to compute basic and diluted net loss per share	67,082,161	44,282,607

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

	March 31, 2021	December 31, 2020(1)
Cash, cash equivalents and investments in marketable securities	\$ 884,912	\$ 735,086
Total assets	935,119	772,292
Total liabilities	270,329	269,988
Total stockholders' equity	664,790	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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Arcus Contact:

Katherine Bock

VP Investor Relations & Corporate Strategy

(510) 694-6231

kbock@arcusbio.com

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