



NEWS RELEASE

Arcus Biosciences Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Operational Highlights

2/24/2021

- Multiple key data read-outs expected for 2021, including the ARC-7 interim analysis in 2Q21
- Domvanalimab's advancement into a registrational study coupled with recent IND clearance for AB308, Arcus's FcR-enabled anti-TIGIT antibody, reinforces Arcus's position as a leader in the anti-TIGIT field
- Promising early data in first-line metastatic pancreatic cancer for AB680, the first small-molecule CD73 inhibitor to enter clinical development, were presented at ASCO GI in 1Q21
- Gilead's recent increased investment in Arcus demonstrates the strength of our ongoing collaboration and Gilead's confidence in Arcus's clinical-stage pipeline and R&D capabilities

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 fourth quarter and year ended December 31, 2020 and provided operational highlights.

"With \$735 million in cash at the end of the year, plus \$220 million from Gilead's recent equity investment, we are extremely well-positioned to accelerate the advancement of our pipeline, initiate our first registrational trials for domvanalimab, and deliver multiple readouts from the randomized portions of our ongoing clinical studies," said Terry Rosen, Ph.D., CEO. "These readouts include the interim analysis for ARC-7, our Phase 2 randomized study evaluating domvanalimab and zimberelimab in first-line, PD-L1 high, non-small cell lung cancer, in the second

quarter of 2021, as well as initial data from our randomized studies evaluating our A2a/A2b adenosine receptor antagonist, etrumadenant. In 2021, we also expect to continue to advance AB680, our CD73 inhibitor, in pancreatic cancer and to expand the clinical program for this first-in-class small molecule to other tumor types. We are also pleased to announce that we received IND clearance for AB308 in January, allowing us to achieve a new milestone with five molecules now in clinical development, and we expect to advance at least one new small molecule program into clinical development in the second half of 2021.”

Corporate and Partnership Updates

- Announced that Gilead increased its ownership in Arcus from approximately 13.0% to 19.5%. The \$220 million received from this investment will enable Arcus to accelerate the development plans for Arcus’s five clinical-stage molecules.
- Continued to advance our clinical collaboration with AstraZeneca for the conduct of PACIFIC-8, a registrational trial designed to evaluate domvanalimab and durvalumab in Stage 3 non-small cell lung cancer (NSCLC). We expect this trial to start in the second half of 2021.
- Expanded our relationship with Wuxi Biologics and Arcus’s portfolio of molecules targeting the ATP-adenosine axis through a licensing and collaboration agreement with WuXi for anti-CD39 antibodies. We expect to file an IND for an antibody from this program in 2022 and to develop it in combination with our first-in-class small molecules targeting other points of intervention in this pathway.
- As part of our option agreement with Taiho for their development and commercialization of Arcus’s molecules in Japan and other territories in Asia (excluding China), Taiho is planning to initiate clinical development of zimberelimab, our anti-PD-1 antibody, to advance assets in their portfolio. To date, Taiho has exercised its option rights to zimberelimab and etrumadenant.

Domvanalimab (FcR-silent TIGIT antibody)

Recent Highlights:

- Initiated ARC-10, Arcus’s first registrational trial , evaluating domvanalimab + zimberelimab vs. zimberelimab vs. chemotherapy in first-line PD-L1 \geq 50%, locally advanced or metastatic NSCLC. This “two-in-one” study involves a single trial to support the potential approvals of both zimberelimab monotherapy and domvanalimab + zimberelimab, and the timing of the study initiation aligns well with the planned interim analysis for ARC-7 in the second quarter. We expect to initiate other registrational trials for domvanalimab later in the year.

Upcoming Milestones:

- Interim analysis from ARC-7 , our randomized, three-arm Phase 2 trial ongoing in the U.S. and Asia, evaluating

zimberelimab + domvanalimab vs. zimberelimab vs. zimberelimab + domvanalimab + etrumadenant in first-line PD-L1 \geq 50% locally advanced or metastatic NSCLC, is expected in the second quarter of 2021, and we plan to provide a directional update on the data at that time. We expect to present data from this analysis at a medical conference in the second half of 2021.

AB680 (CD73 inhibitor)

Recent Highlights:

- Presented promising preliminary data from the dose-escalation portion of ARC-8 , our Phase 1/1b study evaluating AB680 in combination with zimberelimab and gemcitabine/nab-paclitaxel (G/NP) in first-line metastatic pancreatic cancer at the ASCO GI Conference in January.
 - As of the efficacy data cut-off date (DCO) of 12/9/20, 17 patients across the four dose-escalation cohorts (25mg, 50mg, 75mg and 100mg) were evaluable for response. In these patients, the objective response rate (ORR) was 41% (three confirmed partial responses (PRs), four PRs pending a second confirmatory scan). One of the confirmed PRs converted to a complete response after the DCO.
 - The confirmed ORR for Abraxane® (nab-paclitaxel), as stated in its FDA approved label for use in combination with gemcitabine, is 23%. To date, PD-1 antibodies have not shown any benefit when added to G/NP in this setting.^{1,2,3,4}
- Initiated enrollment of the dose-expansion portion of ARC-8 using a dosing regimen of 100mg of AB680 administered intravenously every two weeks. Due to ARC-8's rapid enrollment, we expect to open a control arm of AB680 plus G/NP by the end of this quarter, which will inform the design of a potential registrational trial. We and our investigators continue to be encouraged by the number of responses seen in ARC-8, and if data continue to look promising, we anticipate discussing these data with health authorities later in the year.
- Nearing completion of a study with the oral formulation of AB680 in healthy volunteers. Having both oral and intravenous formulations of AB680 will give us flexibility to customize AB680's dosing regimens based upon the combination partner.
- Initiated enrollment of our first cohort evaluating the combination of AB680 and etrumadenant. This cohort is part of our ongoing ARC-6 metastatic castrate-resistant prostate cancer (mCRPC) platform study. We also intend to evaluate AB680 + etrumadenant combinations in our ARC-9 metastatic colorectal cancer (mCRC) platform study and to evaluate other AB680 combinations in other settings and tumor types.

Upcoming Milestones:

- More mature data from ARC-8 , including data from the dose-escalation and dose-expansion cohorts, are expected to be presented at a medical conference in the second half of 2021.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

Recent Highlights:

- Initiated the Stage 2 randomized portion of the etrumadenant + zimberelimab + docetaxel cohort in ARC-6 , our ongoing Phase 1b/2 platform study evaluating etrumadenant-based combinations in mCRPC. Stage 2 was initiated after passing the Stage 1 futility assessment and is evaluating etrumadenant + zimberelimab + docetaxel vs. a docetaxel control arm.
- Initiated ARC-9 , a randomized Phase 1b/2 platform study to evaluate etrumadenant in combination with other agents in 2L+ mCRC based on intriguing durability and response data, particularly those in late-line mCRC patients, from the ARC-3 study.

Upcoming Milestones:

- Updated data from ARC-3 , including overall survival and progression-free survival data for the 3L+ mCRC cohort, will be presented at the American Association for Cancer Research (AACR) Virtual Meeting being held April 10-15, 2021 (week 1) and May 17-21, 2021 (week 2).
- Initial data from Stage 1 of ARC-6 are expected to be presented in the second quarter of 2021. These data will be from the etrumadenant + zimberelimab + docetaxel cohort in 2L mCRPC in patients that failed androgen deprivation therapy. Initial data from the Stage 2 randomized portion, which compares this etrumadenant combination to docetaxel, are expected to be presented in the second half of 2021.
- Initial randomized data from ARC-4 , our ongoing study evaluating etrumadenant + zimberelimab + chemotherapy vs. zimberelimab + chemotherapy in EGFRmut tyrosine kinase inhibitor (TKI)-relapsed and refractory NSCLC, are expected to be presented at a medical conference in the second half of 2021.

Other Programs

- Received IND clearance for AB308 , Arcus's FcR-enabled anti-TIGIT antibody, in January. We plan to evaluate AB308 in settings where the depletion of TIGIT-bearing cancer cells could be beneficial, such as certain hematological malignancies.
 - Our Phase 1/1b dose-escalation study for AB308, which will leverage Arcus's anti-TIGIT antibody development experience, is designed to quickly establish the safety, pharmacokinetics and pharmacodynamics of AB308 in combination with zimberelimab and could enable the advancement of AB308 into a registrational trial by year-end 2021.
- Initiation of clinical development for our HIF-2a inhibitor is anticipated in the second half of 2021.

Financial Results for the Fourth Quarter and Full Year Ended December 31, 2020

- Cash, cash equivalents and investments were \$735.1 million as of December 31, 2020, compared to \$188.3

million at December 31, 2019. After December 31, 2020, Arcus received an additional \$220.4 million in proceeds from the sale of equity to Gilead. The increase from December 31, 2019 to December 31, 2020 was primarily due to net proceeds of \$326.2 million from the May 2020 public equity offering and \$375 million received upon closing of the Gilead agreements, partially offset by cash utilized for our operations. We expect cash, cash equivalents and investments 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 December 31, 2020, compared to \$9.8 million for the same period in 2019. The revenues in 2020 were comprised of \$7.7 million from our Gilead collaboration and \$1.8 million from our Taiho agreement for both partners' ongoing rights to access our research and development pipeline. The revenues in 2019 were solely from our Taiho agreement and related to \$8.0 million for Taiho's exercise of its option for rights to zimberelimab as well as \$1.8 million for Taiho's ongoing rights to access our research and development pipeline. Collaboration and license revenues were \$77.5 million for the full year ended December 31, 2020, compared to \$15.0 million for the same period in 2019.
- R&D Expenses: Research and development expenses were \$48.7 million for the three months ended December 31, 2020, compared to \$20.7 million for the same period in 2019. The increase was primarily due to increases in manufacturing and clinical costs required to supply and conduct our ongoing clinical studies, as well as increases in employee compensation costs driven by an increase in our headcount, approximately \$2.6 million of which consists of non-cash stock-based compensation. Research and development expenses were \$159.3 million for the full year ended December 31, 2020, compared to \$78.5 million for the same period in 2019.
- G&A Expenses: General and administrative expenses were \$12.8 million for the three months ended December 31, 2020, compared to \$6.6 million for the same period in 2019. The increase in expense was due to increases in employee compensation driven by an increase in headcount, approximately \$2.9 million of which consists of non-cash stock-based compensation costs. Additional increases in legal and accounting expenses resulted from ongoing public company compliance obligations. General and administrative expenses were \$42.4 million for the full year ended December 31, 2020, compared to \$25.2 million for the same period in 2019.
- Net Loss: Net loss was \$51.9 million for the three months ended December 31, 2020, compared to a net loss of \$16.6 million for the same period in the prior year. The increase in net loss was primarily attributable to an increase in operating expenses as noted above. Net loss for the full year ended December 31, 2020 was \$122.9 million, compared to \$84.7 million for the same period in 2019.

Arcus Clinical Trials Referenced Above

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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
PACIFIC-8	Durva ± Dom	Curative-Intent Stage 3 NSCLC	Expected initiation 2H21 Registrational	NA

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

*Randomization is expected to open by end of 1Q21.

1. Von Hoff DD, et al., N Eng J Med. 2013; 369(18):1691.
2. https://packageinserts.bms.com/pi/pi_abraxane.pdf
3. Weiss GJ, et al., Invest New Drugs. 2018; 36(1):96.
4. Zev A., et al., Clin Cancer Res. 2020; 26(18): 4814.

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 ≥ 50% metastatic non-small cell lung cancer (NSCLC) evaluating zimberelimab monotherapy, domvanalimab with zimberelimab and domvanalimab plus etrumadenant with 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 a registrational study, in collaboration with AstraZeneca, evaluating the curative-intent stage 3 NSCLC setting. **AB308**, an anti-TIGIT antibody that is FcR-enabled, is advancing 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 the company and its ability to advance, expand and accelerate the progress of its pipeline and clinical development programs, anticipated milestones and associated timelines and Arcus's expectation that cash, cash equivalents and investments on-hand to 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; our dependence on our collaboration with Gilead for the successful development and commercialization of our investigational products; 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; the 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 annual report on Form 10-K for the year ended December 31, 2020 filed on February 24, 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
(In thousands, except share and per share amounts)

	(Unaudited)		Year Ended	
	Three Months Ended December 31,		December 31,	
	2020	2019	2020	2019
Revenues:				
License revenue	\$ -	\$ 8,000	\$ 55,096	\$ 8,000
Collaboration revenue	9,487	1,750	22,421	7,000
Collaboration and license revenue	9,487	9,750	77,517	15,000
Operating expenses:				
Research and development	48,712	20,686	159,348	78,481

General and administrative	12,787	6,591	42,404	25,228
Total operating expenses	61,499	27,277	201,752	103,709
Income (loss) from operations	(52,012)	(17,527)	(124,235)	(88,709)
Non-operating income (expense):				
Interest and other income, net	159	929	1,377	5,201
Gain on deemed sale from equity method investee	-	-	613	-
Share of loss from equity method investee	-	-	(613)	(1,202)
Total non-operating income, net	159	929	1,377	3,999
Net income (loss)	(51,853)	(16,598)	(122,858)	(84,710)
Other comprehensive income (loss)	(37)	11	(20)	171
Comprehensive loss	\$ (51,890)	\$ (16,587)	\$ (122,878)	\$ (84,539)
Net income loss per share, basic and diluted	\$ (0.82)	\$ (0.38)	\$ (2.24)	\$ (1.93)
Weighted-average number of shares used to compute basic and diluted net loss per share	63,527,932	44,056,407	54,787,118	43,825,991

Selected Consolidated Balance Sheet Data
(In thousands)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and investments in marketable securities	\$ 735,086	\$ 188,270
Total assets	772,292	203,110
Total liabilities	269,988	39,268
Total stockholders' equity	502,304	163,842

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Katherine Bock

VP Investor Relations & Corporate Strategy

(510) 694-6231

kbock@arcusbio.com

Source: Arcus Biosciences, Inc.