



NEWS RELEASE

# Arcus Biosciences Announces Fourth Quarter and Full Year 2019 Financial Results and Corporate Updates

3/5/2020

- Advanced three molecules into randomized Phase 2 trials to evaluate Arcus's potential best-in-class therapies and highly differentiated therapeutic combinations;
  - o Preliminary randomization data expected in 4Q20 for AB928 (the first and only dual A2a/A2b adenosine receptor antagonist in the clinic), AB154 (anti-TIGIT antibody) and zimberelimab (anti-PD1 antibody)
- Entered into a clinical collaboration with Genentech to accelerate development of AB928
- Announced Taiho's option exercise of zimberelimab for its territories; option facilitates global development and commercialization as a monotherapy and as a combination backbone

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), an oncology-focused biopharmaceutical company working to create best-in-class cancer therapies, today announced financial results for the fourth quarter and full year ending December 31, 2019 and provided corporate updates.

"The robust expertise and integrated discovery and clinical organizations at Arcus, combined with the keen foresight of the Arcus team, continue to deliver," said Terry Rosen, Ph.D., Chief Executive Officer. "Early in the genesis of the company, adding both an anti-PD-1 antibody that exhibits clinical activity and safety profiles consistent with those of the currently approved agents and an anti-TIGIT antibody, a potential new immunology backbone therapy, has placed our development program in a particularly strong position. With emerging data reinforcing our leadership in the development of potential therapeutics that modulate the adenosine pathway

and the initiation of a Phase 2 study for our anti-TIGIT antibody AB154, we see the upcoming catalysts in 2020 as important milestones in supporting Arcus's long term vision to consistently create and bring genuinely breakthrough therapies to patients."

## 2019 Key Highlights

- Announced Taiho's exercise of its option for an exclusive license to zimberelimab, an anti-PD1 antibody, for its territories in Japan and other Asian countries (excluding China)
- Initiated ARC-7, a randomized Phase 2 clinical trial of AB154, an anti-TIGIT antibody, for the treatment of non-small cell lung cancer (NSCLC)
  - The trial may support the global filing strategy for AB154 and zimberelimab and will include a zimberelimab monotherapy arm, a doublet combination of AB154 and zimberelimab, and a triplet combination including our dual A2a/A2b adenosine receptor antagonist (AB928) with AB154 and zimberelimab
- Initiated activities for two Phase 2 randomized studies in clinical collaboration with Genentech to accelerate the development of AB928
- Successfully passed futility analysis in the ARC-3 Phase 1b expansion, which will proceed to full enrollment to evaluate the efficacy of AB928 in combination with FOLFOX in colorectal cancer (CRC)
- Presented data from all four of the dose-escalation portions of the AB928 combination trials establishing favorable safety, tolerability and early clinical efficacy, consistent with clinical hypotheses of the ability for AB928 to be combined with different backbone therapies
  - These data provided the foundation for the ongoing Phase 1b/2 efficacy trials in metastatic castrate resistant prostate cancer (mCRPC), CRC, NSCLC, pancreatic (PDAC), triple negative breast and renal cell cancers
- Complemented Arcus's existing Scientific Advisory Board with the formation of a distinguished Clinical Advisory Board (CAB) to further support Arcus's progressing clinical programs. The CAB includes: Johanna C. Bendell, M.D., (Sarah Cannon Research Institute), Matthew D. Hellmann, M.D., (Memorial Sloan Kettering Cancer Center), Antoni (Toni) Ribas, M.D., Ph.D., (University of California-Los Angeles), Naiyer A. Rizvi, M.D., (Columbia University), and Mary-Ellen Taplin, M.D., (Dana-Farber Cancer Institute)
- Appointed internationally renowned physician-scientist, Antoni Ribas, M.D., Ph.D. and biopharmaceutical industry leader Patrick Machado, J.D. to Arcus's Board of Directors

## Anticipated Corporate Milestones & Presentations

- Anticipated Corporate Milestones
  - Initiate ARC-6, a Phase 1b/2 platform trial to evaluate the efficacy and safety of AB928 in multiple

rationally selected combinations for the treatment of mCRPC in the first half of 2020; this will expand our strategy in prostate cancer and build on our current phase 1b expansion cohort

- Preliminary Phase 2 randomization data from the two clinical collaborations with Genentech with AB928 in CRC and PDAC expected in the fourth quarter of 2020
  - Preliminary Phase 2 randomization data with AB154 from the ARC-7 trial in first-line NSCLC expected in the fourth quarter of 2020
  - Preliminary Phase 1b expansion data with AB928 in multiple tumor types expected starting in mid-2020
  - Phase 1a dose-escalation data in the ARC-8 trial evaluating AB680, the first small-molecule CD73 inhibitor to enter the clinic, in combination with zimberelimab and gemcitabine/nab-paclitaxel in patients with PDAC, anticipated starting in mid-2020; Phase 1b expansion cohort anticipated to start in mid-2020
  - Clinical studies with at least two new therapeutic candidates from existing development programs (PI3Ky; HIF-2 $\alpha$ ; Axl; PAK4) planned to begin in late 2020/early 2021
- Upcoming Presentations
    - American Association for Cancer Research (AACR) Annual Meeting 2020; San Diego Convention Center, San Diego, CA; April 24-29, 2020
      - Abstract Number LB-387: Efficacy and Safety of AB928 plus modified FOLFOX-6 (mFOLFOX-6) in Participants with Metastatic Colorectal Cancer (mCRC): Initial Results at the Recommended Dose for Expansion (ARC-3)
      - Abstract Number 393: Dual A2aR/A2bR antagonism with AB928 suppresses the effects of adenosine on both immune and cancer cells in the tumor microenvironment
      - Abstract Number 6649: Inhibiting adenosine signaling and KRAS enhances the effect of  $\alpha$ -PD-1 therapy in a KRASG12C/TP53R172H/+ pancreatic cancer model
      - Abstract Number 686: Selective inhibition of hypoxia-inducible factor (HIF)-2 $\alpha$  for cancer
      - Abstract Number 4214: Discovery and characterization of potent and selective AXL receptor tyrosine kinase inhibitors for cancer therapy

Please refer to Arcus's pipeline at [www.arcusbio.com](http://www.arcusbio.com) for the company's most current pipeline and development plans.

## Financial Results for the Fourth Quarter and Full Year Ended December 31, 2019

- Cash, cash equivalents and investments in marketable securities were \$188.3 million as of December 31, 2019, compared to \$259.7 million at December 31, 2018. The decrease was due to the utilization of cash to fund our research, development and administrative operations. Based on our current operating plans, we anticipate that our cash, cash equivalents and investments will be sufficient to fund operations into 2021.

- Revenues: Collaboration and license revenue was \$9.8 million for the fourth quarter of 2019 and \$15.0 million for the year ended December 31, 2019, compared to \$1.6 million and \$8.4 million, respectively, for the same periods in 2018. The increase in revenue during the fourth quarter as compared to the same period of the prior year was primarily due to Taiho Pharmaceutical's exercise of its option for our anti-PD-1 antibody program, including zimberelimab. The increase in revenue for the full year 2019 as compared to 2018 is primarily due to Taiho's exercise of its option for our anti-PD-1 antibody program, including zimberelimab, and an upward remeasurement of the initial transaction price for our existing agreement with Taiho following our adoption in 2019 of the new GAAP revenue accounting standard, ASC 606. The overall increase for the full year 2019 is partially offset by a \$3.0 million fee that we recognized in 2018 following Taiho's exercise of its option for our adenosine receptor antagonist program (AB928).
- R&D Expenses: Research and development expenses were \$20.7 million for the fourth quarter of 2019 and \$78.5 million for the year ended December 31, 2019, compared to \$11.4 million and \$49.6 million, respectively, for the same periods in 2018. The increase in research and development expenses was primarily due to an increase in clinical activities to support our four programs in clinical development and an increase in R&D headcount and related costs.
- G&A Expenses: General and administrative expenses were \$6.6 million for the fourth quarter of 2019 and \$25.2 million for the year ended December 31, 2019, compared to \$3.6 million and \$13.6 million, respectively, for the same periods in 2018. The increase in general and administrative expenses was primarily due to an increase in G&A headcount and related costs, as well as additional compliance costs related to operations as a public company.
- Net Loss: Net loss was \$16.6 million for the fourth quarter of 2019 and \$84.7 million for the year ended December 31, 2019, compared to \$12.3 million and \$49.6 million for the same periods in 2018, respectively. The increase in net loss as compared to the prior periods was primarily attributable to an increase in operating expenses as noted above.

## 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 need. **AB928**, the first and only dual A2a/A2b adenosine receptor antagonist in the clinic, is being evaluated in several Phase 1b/2 studies across multiple indications, including prostate, colorectal, non-small cell lung, pancreatic, triple negative breast and renal cell cancers. **AB680**, the first CD73 small-molecule inhibitor in the clinic, is in Phase 1/1b development for the treatment of first-line metastatic pancreatic cancer. **AB154**, an anti-TIGIT monoclonal antibody, is in Phase 2 development for the treatment of first-line metastatic non-small cell lung cancer in combination with zimberelimab and AB928. **Zimberelimab (AB122)**, Arcus's anti-PD1 monoclonal antibody, is being evaluated in a Phase 1b study as monotherapy for cancers with no approved

anti-PD1 treatment options, as well as in combinations across the portfolio. For more information about Arcus Biosciences, please visit [www.arcusbio.com](http://www.arcusbio.com).

## Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including, but not limited to, Arcus's expectations regarding anticipated milestones and timelines, as well as anticipated operating expenses and capital expenditure requirements, 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 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, 2019 filed on March 5, 2020 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.

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,	
	2019	2018	2019	2018
Collaboration and license revenue	\$ 9,750	\$ 1,562	\$ 15,000	\$ 8,353
Operating expenses:				
Research and development	20,686	11,436	78,481	49,646
General and administrative	6,591	3,610	25,228	13,566
Total operating expenses	<u>27,277</u>	<u>15,046</u>	<u>103,709</u>	<u>63,212</u>
Loss from operations	(17,527)	(13,484)	(88,709)	(54,859)
Non-operating income (expense):				
Interest and other income, net	929	1,512	5,201	4,922
Gain on deemed sale from equity method investee	-	-	-	1,229
Share of loss from equity method investee	-	(323)	(1,202)	(886)
Total non-operating income, net	<u>929</u>	<u>1,189</u>	<u>3,999</u>	<u>5,265</u>
Net loss	<u>(16,598)</u>	<u>(12,295)</u>	<u>(84,710)</u>	<u>(49,594)</u>
Other comprehensive income (loss)	11	1	171	(65)

Comprehensive loss	\$ (16,587)	\$ (12,294)	\$ (84,539)	\$ (49,659)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.28)	\$ (1.93)	\$ (1.43)
Weighted-average number of shares used to compute basic and diluted net loss per share	<u>44,056,407</u>	<u>43,163,412</u>	<u>43,825,991</u>	<u>34,618,237</u>

Selected Consolidated Balance Sheet Data  
(In thousands)

	As of December 31,	
	2019	2018
Cash, cash equivalents and investments in marketable securities	\$ 188,270	\$ 259,725
Total assets	203,110	274,925
Total liabilities	39,268	39,983
Total stockholders' equity	163,842	234,942

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20200305005818/en/>

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Source: Arcus Biosciences, Inc.