



NEWS RELEASE

Gilead and Arcus Announce Amended Collaboration and Equity Investment

1/29/2024

– Investment Reinforces Companies’ Conviction in TIGIT Pathway and Provides Opportunity to Accelerate the Anti-TIGIT Program –

– Additional Equity Investment of \$320M, Raising Gilead’s Ownership Stake in Arcus to 33% –

– Amendment Provides Gilead with One Additional Seat on the Arcus Board –

FOSTER CITY, Calif. & HAYWARD, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) and Arcus Biosciences, Inc. (NYSE: RCUS) today announced an amendment to their collaboration agreement and a separate equity investment by Gilead of \$320 million in Arcus common stock at \$21.00 per share. The equity investment and collaboration amendment enable accelerated growth of the companies’ joint development programs that span multiple indications. Additionally, Johanna Mercier, Chief Commercial Officer at Gilead Sciences, will join the Arcus Board, bringing Gilead’s total director designees to three. The amendment also includes governance enhancements enabling streamlined decision-making and reflecting the continued growth of the collaboration.

“This amendment allows Gilead to accelerate the domvanalimab program and enables Arcus to focus on progressing multiple pipeline assets, including both Gilead-optioned and non-optioned programs,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “We look forward to strengthening our collaboration as we explore the collective power of our cross-portfolio combinations to help transform how cancer is treated.”

Gilead and Arcus have reprioritized the joint domvanalimab development program to focus on advancing and



potentially accelerating the Phase 3 studies STAR-121 (lung cancer) and STAR-221 (gastrointestinal cancer), which are both expected to be fully enrolled by year-end. This prioritization focuses on domvanalimab-containing regimen research in areas where it may have significant impact in combination with chemotherapy and in settings with high unmet need through all-comer study designs. The companies also plan to initiate STAR-131, a new registrational Phase 3 lung cancer study that includes the domvanalimab plus zimberelimab regimen. This prioritization reflects the companies' continued conviction in the TIGIT pathway and the Fc-silent design of domvanalimab, which has the potential for differentiation in both efficacy and safety.

"Since the inception of our partnership with Gilead in 2020, the companies have moved increasingly closer in all aspects of our research and development efforts," said Terry Rosen, PhD, Chief Executive Officer, Arcus. "This investment and prioritization enable both companies to leverage their respective strengths and focus on efficiently advancing novel combinations that have the potential to change the landscape of cancer treatment. The additional investment by Gilead, which extends our cash runway into 2027, will enable us to fund our Phase 3 studies of quemliclustat in pancreatic cancer and AB521 in kidney cancer, as well as to begin preparation for our first potential product approvals."

Additional changes during this prioritization will include discontinuing further enrollment in the Phase 3 ARC-10 study evaluating domvanalimab plus zimberelimab compared to pembrolizumab monotherapy in first-line locally advanced or metastatic, PD-L1-high NSCLC. The discontinuation of the ARC-10 study is based on strategic prioritization to advance and potentially accelerate the Phase 3 studies STAR-121 and STAR-221, which have the potential to address a higher unmet need for patients with lung and gastrointestinal cancers.

Gilead and Arcus are grateful to the patients and investigators who have made the choice to participate in ARC-10, which will continue to generate data and insights that will be shared at future scientific conferences. Patients currently enrolled in ARC-10, or who consented prior to January 29, 2024, and choose to enroll in the study, may continue their treatment and be monitored according to the study protocol. No changes to the safety and efficacy profile of domvanalimab and zimberelimab have been observed.

Also, under the terms of the amended collaboration agreement, the planned Phase 3 first-line study in pancreatic cancer evaluating the investigational small molecule CD73 inhibitor quemliclustat will become an Arcus independent study.

Domvanalimab, zimberelimab and quemliclustat are investigational molecules. Neither Gilead nor Arcus has received approval from any regulatory authority for any use of these molecules, and their safety and efficacy for the treatment of lung, gastrointestinal and pancreatic cancers have not been established.

[About Domvanalimab](#)

Domvanalimab is the first Fc-silent investigational monoclonal antibody in pivotal trials which was designed to block and bind to the T-cell immunoreceptor with Ig and ITIM domains (TIGIT), a protein on immune cells that acts as a brake on the immune response. Cancer cells can exploit TIGIT to avoid detection by the immune system. By binding to TIGIT, domvanalimab is designed to free up immune activating pathways and activate immune cells to attack and kill cancer cells. Domvanalimab has demonstrated complete target coverage on all TIGIT-expressing immune cells in the blood of patients.

Domvanalimab is being evaluated in three registrational Phase 3 studies across lung and gastrointestinal cancers, including: (1) STAR-121, evaluating domvanalimab plus zimberelimab and chemotherapy versus pembrolizumab plus chemotherapy in first-line all-comer NSCLC regardless of PD-L1 expression levels; (2) STAR-221, evaluating domvanalimab plus zimberelimab and chemotherapy versus nivolumab plus chemotherapy in first-line locally advanced, unresectable or metastatic gastric, esophageal and gastro-esophageal junction adenocarcinomas; and (3) PACIFIC-8, being operationalized by AstraZeneca, evaluating domvanalimab plus durvalumab in unresectable Stage 3 NSCLC.

About Zimberelimab

Zimberelimab is an anti-programmed cell death protein-1 (PD-1) monoclonal antibody that binds PD-1, with the goal of restoring the antitumor activity of T cells. As a differentiated next-generation, fully human antibody, zimberelimab has demonstrated high affinity, selectivity and potency in various tumor types.

Guangzhou Gloria Biosciences Co. Ltd., who holds commercialization rights for zimberelimab in greater China, has obtained approval for zimberelimab as the first and only anti-PD-1 antibody to treat recurrent or metastatic cervical cancer (September 2023). Additionally, in China, zimberelimab is approved to treat relapsed or refractory classical Hodgkin's lymphoma (August 2021). Zimberelimab is not approved for any use in the U.S. or other regions outside of China. Gloria conducts its development and commercialization activities independent of Arcus and Gilead.

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 collaborators, 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 multiple investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis (CD73 and dual A2a/A2b receptor), HIF-2a, CD39 and AXL. For more information about Arcus

Biosciences' clinical and preclinical programs, please visit www.arcusbio.com.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, COVID-19, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

Arcus Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the future contained herein 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, including, but not limited to, the statements regarding: the initiation of new studies and continuation or discontinuation of existing studies and indications; the ability of Arcus to advance its pipeline; Arcus's expectations regarding the completion of enrollment of STAR-121 and STAR-221 in 2024; Arcus's expectations regarding the extension of its cash runway into 2027; and the potential of domvanalimab-containing regimens to be differentiated and potentially transformative in the treatment of certain cancers. 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: dependence on the collaboration with Gilead for the successful development and commercialization of Arcus's investigational products, including domvanalimab and zimberelimab; difficulties associated with the management of the collaboration activities or expanded clinical programs; the emergence of new or unexpected adverse events or unfavorable results from ongoing or future clinical trials with domvanalimab, zimberelimab or quemliclustat; the inherent uncertainty associated with pharmaceutical product development and clinical trials; delays in Arcus's clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; and changes in the competitive landscape for Arcus's programs. Risks and uncertainties facing Arcus are described more fully in the "Risk Factors" section of Arcus's most recent periodic report that has been filed with the U.S. Securities and Exchange Commission. 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.

Gilead Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that Gilead may not realize the potential benefits of amended collaboration and investment agreement with Arcus or its other investments in oncology; difficulties or unanticipated expenses in connection with the collaboration and the potential effects on Gilead's revenues and earnings; the risk that Gilead's investment in Arcus will lose value for any number of reasons; the ability of the parties to initiate, progress or complete clinical trials within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing or additional clinical trials, including those involving domvanalimab, zimberelimab and/or quemliclustat (such as STAR-121, STAR-131, STAR-221 and PACIFIC-8); uncertainties relating to regulatory applications for these and other candidates and related filing and approval timelines; Gilead's ability to receive regulatory approvals for such candidates in a timely manner or at all, and the risk that any such approvals may be subject to significant limitations on use; the possibility that the parties may make a strategic decision to terminate the collaboration at any time, or to discontinue development of programs for indications currently under evaluation and as a result, such programs and/or indications may never be commercialized; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

The Arcus name and logo are trademarks of Arcus Biosciences, Inc., and Gilead and the Gilead logo are trademarks of Gilead Sciences, Inc., or its related companies.

For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on X/Twitter (@GileadSciences) and LinkedIn (@Gilead-Sciences).

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