



NEWS RELEASE

# Gilead and Arcus Biosciences Announce Positive Update on Joint TIGIT Program From Interim Analysis of ARC-7 Study in Non-small Cell Lung Cancer

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- Fourth Interim Analysis Shows Continued Clinically Meaningful Differentiation Across All Efficacy Measures, Including PFS, in Both Domvanalimab-Containing Arms Compared to the Anti-PD-1 Zimberelimab Monotherapy Arm in First-Line NSCLC Patients –
- Data will be Presented on December 20, 2022 at the American Society of Clinical Oncology (ASCO) Monthly Plenary Series –
- Three Phase 3 Domvanalimab Combination Studies in NSCLC are Ongoing –

FOSTER CITY, Calif. & HAYWARD, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) and Arcus Biosciences (NYSE: RCUS) today announced a positive update from the fourth interim analysis of the randomized, open-label Phase 2 ARC-7 study in patients with first-line metastatic non-small cell lung cancer (NSCLC) with PD-L1 tumor proportion score (TPS)  $\geq 50\%$  without epidermal growth factor receptor or anaplastic lymphoma kinase (EGFR/ALK) mutations. ARC-7 is evaluating the combinations of anti-TIGIT antibody domvanalimab plus anti-PD-1 antibody zimberelimab (doublet), and domvanalimab plus zimberelimab and etrumadenant, an A2a/b adenosine receptor antagonist (triplet), versus zimberelimab alone, and represents the first randomized Phase 2 study of an Fc-silent anti-TIGIT/anti-PD-1 combination. The protocol-specified fourth interim analysis was conducted when the trial reached full enrollment, with a clinical data cutoff date of August 31, 2022. A total of 150 patients have been randomized across the three study arms.

For the current interim analysis, efficacy was evaluated in study patients who had at least 13 weeks of potential follow-up and were eligible for at least two imaging scans (n=133). Both domvanalimab combinations continued to show clinically meaningful differentiation compared to zimberelimab monotherapy across multiple efficacy measures, including objective response rates (ORR), progression-free survival (PFS) and six-month landmark PFS.

“The efficacy measures observed, including PFS, reinforce confidence in the TIGIT pathway. The interim results show that combining two checkpoint inhibitors – an anti-TIGIT and an anti-PD-1 – delivered added benefit beyond anti-PD-1 monotherapy in this setting,” said Melissa L. Johnson, M.D., Director Lung Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, and Lead Investigator for the ARC-7 study. “These data are important for the lung cancer research field, and I look forward to presenting the dataset at the upcoming virtual ASCO Monthly Plenary on December 20th.”

At time of data cutoff, no unexpected safety signals were observed across the three study arms. Both domvanalimab-containing arms were generally well tolerated and showed an overall safety profile consistent with the known safety profiles for each individual molecule to date.

“We are thrilled that Dr. Melissa Johnson will present the full results for the current interim analysis of ARC-7, including ORR, PFS and disease control rate, in the coming weeks, given the importance of these data for the immuno-oncology field,” said Dmitry S.A. Nuyten, M.D., Ph.D., Chief Medical Officer of Arcus Biosciences. “The consistency of the efficacy and safety data from both of the domvanalimab-containing arms observed at this interim analysis support our continued strong conviction in the domvanalimab program.”

“These results strengthen our belief in the potential of domvanalimab and the promise of our anti-TIGIT approach to meaningfully impact the outlook for people with metastatic lung cancer,” said Bill Grossman, M.D., Ph.D., Senior Vice President, Therapeutic Area Head, Gilead Oncology. “We will continue to accelerate our TIGIT development program with Arcus, with four ongoing registrational studies in NSCLC and upper GI malignancies.”

Detailed results from this fourth interim analysis and an exploratory analysis on 12 patients who crossed over from zimberelimab monotherapy arm to triplet therapy will be presented on December 20, 2022, at the Monthly Plenary Series, a new virtual forum for presentation and discussion of the latest cancer research. According to ASCO, live presentations are accessible to virtual attendees and available on-demand, and abstract presentations are accompanied by a discussant presentation and followed by a live Q&A session. Abstracts accepted for the Monthly Plenary Session are also placed at the ASCO Annual Meeting in June 2023. During the ASCO Annual Meeting, additional results from further analysis of the ARC-7 dataset will be presented.

Domvanalimab, zimberelimab and etrumadenant are investigational molecules and neither Arcus or Gilead have received approval from any regulatory authority for any use globally, including for the treatment of lung cancer.

Their efficacy and safety for the treatment of lung cancer have not been established.

### About the ARC-7 Study

The ARC-7 study is a Phase 2, multicenter, 3-arm, randomized open-label study evaluating the safety and efficacy of anti-TIGIT antibody domvanalimab plus anti-PD-1 antibody zimberelimab (doublet) versus domvanalimab plus zimberelimab and etrumadenant (triplet), an A2a/b adenosine receptor antagonist, versus zimberelimab alone in 150 patients with first-line metastatic non-small cell lung cancer with PD-L1 TPS  $\geq 50\%$  and no EGFR or ALK mutations. Patients are randomized 1:1:1 across the three study arms, and patients who progress on zimberelimab monotherapy may cross over to receive the triplet. At the time of the fourth interim analysis, 133 patients had at least 13 weeks of potential follow-up (eligible for at least two tumor assessments). The co-primary endpoints are objective response rate and progression-free survival per Response Evaluation Criteria in Solid Tumors (RECIST 1.1). Secondary endpoints include duration of response, disease control rate, overall survival and safety. More information about ARC-7 is available at <https://clinicaltrials.gov/ct2/show/NCT04262856>.

### About Domvanalimab

Domvanalimab is an Fc-silent investigational monoclonal antibody that is designed to bind 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. By binding to TIGIT, domvanalimab is expected to free up immune activating pathways and activate immune cells to attack and kill targeted cells. Domvanalimab is being evaluated in four registrational Phase 3 studies across lung and gastrointestinal cancers, including: (1) ARC-10, evaluating domvanalimab plus zimberelimab versus pembrolizumab in first-line locally advanced or metastatic PD-L1  $\geq 50\%$  NSCLC; (2) PACIFIC-8, being operationalized by AstraZeneca, evaluating domvanalimab plus durvalumab in unresectable Stage 3 NSCLC; (3) STAR-121, evaluating domvanalimab plus zimberelimab and chemotherapy versus pembrolizumab plus chemotherapy in first-line PD-L1 unselected NSCLC; and (4) 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.

### 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 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 six investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis

(CD73 and dual A2a/A2b receptor) and HIF-2a. For more information about Arcus Biosciences' clinical and pre-clinical programs, please visit [www.arcusbio.com](http://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 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, including, but not limited to, statements regarding future data disclosures and presentations, the development of current and future programs, and the efficacy and the safety of domvanalimab, zimberelimab or etrumadenant 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: dependence on the collaboration with Gilead for the successful development and commercialization of Arcus's investigational products, including domvanalimab, zimberelimab and etrumadenant; difficulties associated with the management of the collaboration activities or expanded clinical programs; risks associated with preliminary and interim data not being guarantees that future data will be similar; 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 its quarterly report on Form 10-Q for the quarter ended September 30, 2022, filed on November 2, 2022, 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.

## 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 Gilead's ability 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, etrumadenant and/or zimberelimab; 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 indications 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 Gilead may make a strategic decision to discontinue development of these candidates and as a result, domvanalimab, etrumadenant and/or zimberelimab may never be commercialized; the risk that Gilead may not realize the potential benefits of its collaboration 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; 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, 2022, 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.

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For more information about Gilead, please visit the company's website at [www.gilead.com](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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