NEWS RELEASE

Anti-TIGIT Domvanalimab-Containing Study Arms Improve Progression-Free Survival Compared to Anti-PD1 Alone in Phase 2 Non-Small Cell Lung Cancer Study

12/19/2022

– 35-45% Reduction in Risk of Progression or Death and a Doubling of mPFS Were Observed in the Domvanalimab-Containing Study Arms, Compared to Zimberelimab Monotherapy in First-Line, PD-L1-High NSCLC –

– With Median Follow-Up of Approximately 12 Months, Both Domvanalimab-Containing Study Arms Also Improved ORR and Six-Month Landmark PFS Compared to Zimberelimab Monotherapy –

– Detailed Results Will Be Presented on December 20at 3pm ET / 12pm PT during the ASCO Monthly Plenary Series –

FOSTER CITY, Calif. & HAYWARD, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) and Arcus Biosciences, Inc. (NYSE: RCUS) today announced positive results from the fourth interim analysis of the ARC-7 study in patients with first-line, metastatic non-small cell lung cancer (NSCLC) with PD-L1 tumor proportion score (TPS) ≥50% without epidermal growth factor receptor or anaplastic lymphoma kinase (EGFR/ALK) mutations. ARC-7 is a Phase 2, multicenter, three-arm, randomized, open-label study evaluating the combinations of Fc-silent anti-TIGIT monoclonal antibody domvanalimab plus anti-PD-1 monoclonal antibody zimberelimab (doublet) and domvanalimab plus zimberelimab and etrumadenant, an A2a/b adenosine receptor antagonist (triplet), versus

zimberelimab monotherapy. These results will be presented tomorrow during the American Society of Clinical Oncology (ASCO) Monthly Plenary Series,a new, virtual forum for presentation and discussion of the latest cancer research.

“It is particularly encouraging to see that combination treatments may offer potentially meaningful advances for people with non-small cell lung cancer based on the largest, prospectively randomized Phase 2 study of anti-TIGIT and anti-PD1 antibodies to date,” 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. “The preliminary improvements observed for each of the doublet and triplet regimens across multiple efficacy measures reinforce our confidence in the potential therapeutic benefit of inhibiting the TIGIT pathway and provide further support for the ongoing Phase 3 studies.”

At the time of data cutoff, efficacy was evaluated in patients who had at least 13 weeks of follow-up and were therefore potentially eligible for at least two imaging scans (n=133), and safety was evaluated in all enrolled patients (n=149). With a median follow-up time for efficacy duration of approximately 12 months, both the doublet and triplet combinations demonstrated clinically meaningful improvements in median progression-free survival (PFS) and six-month landmark PFS rates compared to zimberelimab monotherapy, with a 45% reduction in risk of disease progression or death for the doublet and 35% for the triplet.

Each of the domvanalimab-containing study arms also demonstrated clinically meaningful improvements in objective response rate (ORR) compared to zimberelimab monotherapy. Confirmed ORR was 27%, 41% and 40% for the zimberelimab monotherapy arm and the domvanalimab-doublet and -triplet arms, respectively. While the triplet arm did not show an improvement over the doublet arm, it reinforces the results observed in the doublet arm, and the study will continue to monitor PFS, as well as overall survival, for the triplet arm as these data mature.

The efficacy results including ORR and PFS are summarized in the table below:

Endpoint	zimberelimab (Z) monotherapy (n=44)	domvanalimab + zimberelimab (DZ) (n=44)	etrumadenant + domvanalimab + zimberelimab (EDZ) (n=45)
Progression-free Survival (PFS)			
Median in Months (95% CI)	5.4 (1.8, 9.6)	12.0 (5.5, NE)	10.9 (4.8, NE)
Hazard Ratio* (95% CI)		0.55 (0.31, 1.0)	0.65 (0.37, 1.1)
Six-month PFS rate (95% CI)	43% (27, 59)	65% (49, 80)	63% (48, 78)
Objective Response Rate (ORR)			
ORR+ (95% CI)	27% (15.0, 42.8)	41% (26.3, 56.8)	40% (25.7, 55.7)

* Hazard ratio is for comparing domvanalimab-containing study arms to zimberelimab monotherapy.
+ Based on confirmed response per RECIST 1.1
NE=not evaluable

“Results from this randomized and controlled Phase 2 trial in a large number of patients validate the potential for an anti-TIGIT/anti-PD-1 combination to improve outcomes for patients with metastatic NSCLC,” said Dimitry S.A. Nuyten, M.D., Ph.D., Chief Medical Officer of Arcus Biosciences. “Arcus has been at the forefront of developing differentiated combination therapies, and these data are important for patients in need of potential new options, the oncology community’s understanding of TIGIT and for Arcus as a leader in the discovery and development of innovative therapeutics.”

“As these data mature, we continue to see meaningful differentiation with domvanalimab across several measures of efficacy,” said Bill Grossman, M.D., Ph.D., Senior Vice President, Therapeutic Area Head, Gilead Oncology. “These results reinforce the potential opportunity for anti-TIGIT treatments to provide benefit for people with lung cancer and other challenging tumors. We remain committed to accelerating our joint development program with Arcus across our four registrational Phase 3 studies.”

No unexpected safety signals were observed across the three study arms at the time of data cutoff. The domvanalimab-containing study arms appeared to be generally well tolerated and showed an overall safety profile consistent with the known safety profiles of each individual molecule to date. Grade ≥3 treatment-emergent adverse events occurred in 58% of participants in the zimberelimab monotherapy study arm, 47% of the doublet arm, and 52% of the triplet arm. Incidence of infusion-related reactions was low across all treatment arms: 4%, 4% and 10% for zimberelimab monotherapy and the domvanalimab-doublet and -triplet arms, respectively. Immune-related adverse events, including the incidences and grades of rash and pruritus, were generally low and manageable with topical corticosteroids.

This interim analysis was conducted as of the clinical data cutoff date of August 31, 2022, with a total of 150 patients randomized across the three study arms. Patients in the study will continue to receive treatment per protocol, and an updated analysis including efficacy evaluation for all 150 patients is expected to be presented at the ASCO Annual Meeting in June 2023. The protocol-specified primary PFS analysis will be conducted later in 2023 once a specified number of events are achieved.

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

Webinar

At 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time on Tuesday, December 20, 2022, Gilead and Arcus executives will co-host a webinar to discuss the ARC-7 Plenary findings. The live webcast can be accessed via the Investor link on **www.gilead.com** or on **www.arcusbio.com**. The webinar will be archived for at least 30 days following the presentation.

About the ARC-7 Study

The ARC-7 study is a Phase 2, multicenter, three-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 monotherapy in 150 patients with first-line metastatic non-small cell lung cancer (NSCLC) with PD-L1 TPS ≥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 this interim analysis, 133 patients had at least 13 weeks of follow-up (potentially 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. ARC-7 is a proof of concept study to assess the safety and efficacy of domvanalimab-containing study arms over zimberelimab monotherapy. 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 cancer 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 ≥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 advanced six investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis (CD73 and A2a/A2b receptors) and HIF-2a. 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 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, the efficacy and the safety of domvanalimab, zimberelimab or etrumadenant and the potential benefit of product candidates 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.

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

Gilead Contacts:

Jacquie Ross, Investors
investor_relations@gilead.com

Meaghan Smith, Media

Public_affairs@gilead.com

Arcus Contact:

Pia Banerjee, Investors

pbanerjee@arcusbio.com, (617) 459-2006

Holli Kolkey, Media

hkolkey@arcusbio.com, (650) 922-1269

Source: Arcus Biosciences