



NEWS RELEASE

# Gilead and Arcus Announce Anti-TIGIT Domvanalimab Continues to Demonstrate Consistent Improvement in Progression-Free Survival in Non-Small Cell Lung Cancer Study

6/3/2023

- Clinically Meaningful Reduction in Risk of Progression or Death Was Observed in the Domvanalimab-Containing Study Arms Compared to Zimberelimab Monotherapy in First-Line, PD-L1-High NSCLC -
- Objective Response Rate (ORR) Improved in Both Domvanalimab-Containing Study Arms Compared to Zimberelimab Monotherapy -
- Results Will Be Presented Today During the American Society of Clinical Oncology (ASCO) Annual Meeting -

FOSTER CITY, Calif., & HAYWARD, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) and Arcus Biosciences, Inc. (NYSE: RCUS) today announced updated results from an 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)  $\geq 50\%$  without epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations. ARC-7 is the first Phase 2, 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 today during the ASCO Plenary Series: Rapid Abstract Updates session by Melissa L.

Johnson, M.D., Director, Lung Cancer Research, Sarah Cannon Research Institute, and Lead Investigator for the ARC-7 study. Arcus will post the updated ARC-7 results, which will include the data presented at Dr. Johnson's session, as well as additional data, on its website on the corporate presentation page at 5:30pm PDT.

"Progression-free survival curves showed early separation of both domvanalimab-containing arms from the zimberelimab arm, which was consistently maintained, and supports the potential therapeutic benefit of inhibiting the TIGIT pathway," said Melissa L. Johnson, M.D., Director, Lung Cancer Research, Sarah Cannon Research Institute, and Lead Investigator for the ARC-7 study. "I was also encouraged by the consistency of meaningful improvements across other outcome measures for the domvanalimab-containing arms. I look forward to continuing to work with Gilead and Arcus on the dom-zim combinations."

At the time of data cutoff (DCO), February 7, 2023, safety and efficacy were evaluated in all patients randomized and treated (n=150). With a median follow-up time of approximately 18 months, both domvanalimab-containing study arms demonstrated sustained, clinically meaningful improvements in progression-free survival (PFS) compared to zimberelimab monotherapy, with a 33% reduction in risk of disease progression or death for the doublet and 28% for the triplet.

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

Endpoint	zimberelimab (Z) monotherapy (n=50)	domvanalimab + zimberelimab (DZ) (n=50)	etrumadenant + domvanalimab + zimberelimab (EDZ) (n=50)
<b>Progression-Free Survival (PFS)</b>			
Median in Months (95% CI)	5.4 (2.7, 9.7)	9.3 (4.1, NE)	9.9 (4.8, 14.6)
Hazard Ratio* (95% CI)		0.67 (0.4, 1.13)	0.72 (0.63, 1.8)
Six-month PFS rate (95% CI)	45% (30, 59)	58% (43, 72)	62% (48, 76)
12-month PFS rate (95% CI)	25% (11, 40)	41% (26, 56)	44% (29, 59)
<b>Objective Response Rate (ORR)</b>			
ORR+ Confirmed + Pending (95% CI)	15 (30%) [17.9%, 44.6%]	20 (40%)+ [26.4%, 54.8%]	22 (44%) [30%, 58.7%]
Complete Response	1 (2%)	1 (2%)	0 (0%)
Partial Response Confirmed	14 (28%)	18 (36%)	22 (44%)
Partial Response Pending	0 (0%)	1 (2%)	0 (0%)
Stable Disease	16 (32%)	18 (36%)	16 (32%)
Progressive Disease	12 (24%)	4 (8%)	7 (14%)
Not Evaluable (NE)	7 (14%)	8 (16%)	5 (10%)

CI=Confidence Interval

\*Comparing DZ and EDZ arms to Z monotherapy.

+Per RECIST 1.1

++Across all arms, one participant in the DZ arm had a response pending confirmation, which was confirmed after DCO date.

- Preliminary duration of response (DoR) analyses favor domvanalimab-containing arms, with median DoR (range, '+' censored) as follows: Z: 13.2mo (+1.4-+19.4), DZ: not reached (2.8-+26.6), EDZ: 23.7mo (2.6-23.7).

- As of the DCO, approximately twice as many participants remain on study treatment in the domvanalimab-containing arms compared to zimberelimab monotherapy [Z: (n=9), DZ: (n=17), EDZ: (n=20)].

- Consistent ORR and PFS improvements were shown for the domvanalimab-containing arms in a post-hoc analysis of centrally confirmed PD-L1-high

patients.

“At this analysis, the domvanalimab-containing study arms continued to show improved efficacy across multiple measures and both the doublet and triplet arms were generally well tolerated,” said Dimitry S.A. Nuyten, M.D., Ph.D., Chief Medical Officer of Arcus Biosciences. “These data reinforce our confidence in the domvanalimab program.”

“The ARC-7 proof-of-concept study has critically advanced our understanding of the activity of domvanalimab, the first Fc-silent anti-TIGIT monoclonal antibody in pivotal trials,” said Bill Grossman, M.D., Ph.D., Senior Vice President, Therapeutic Area Head, Gilead Oncology. “We look forward to quickly advancing our four ongoing Phase 3 registrational programs in NSCLC and upper GI cancers.”

No unexpected safety signals were observed across the three study arms at the time of DCO. 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. Incidence of infusion-related reactions was low across all treatment arms: 4%, 4% and 12% for zimberelimab monotherapy and the domvanalimab-doublet and -triplet arms, respectively. The addition of domvanalimab to zimberelimab did not increase the incidence of infusion-related reactions, consistent with the Fc-silent design of domvanalimab.

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.

### About the ARC-7 Study

The ARC-7 study is the first 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  $\geq$ 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 this interim analysis, 150 patients had a median follow-up of 18.5 months. 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 the first Fc-silent investigational monoclonal antibody in pivotal trials that is designed to block and bind to the T-cell immunoreceptor with Ig and ITIM domains (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 has demonstrated complete receptor coverage on all TIGIT-expressing peripheral leukocytes.

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 advanced multiple 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](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 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 statements regarding: future data disclosures and presentations, the development and advancement of the TIGIT program, including the four ongoing Phase 3 studies, the therapeutic benefit, including the efficacy and the safety, of Arcus's product candidates. 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 March 31, 2023, filed on May 9, 2023, 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; the possibility that Gilead may make a strategic decision to discontinue development of these product candidates for any indications that are currently under investigation, and as a result, domvanalimab, etrumadenant and/or zimberelimab may never be commercialized for such indications; uncertainties relating to regulatory applications for these and other candidates and related filing and approval timelines; the risk that any regulatory approvals, if granted, may be subject to significant limitations on use; 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 March 31, 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.

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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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