NEWS RELEASE

# Arcus Biosciences Completes Patient Enrollment in Phase 3 Trial Evaluating a Domvanalimab-Containing Regimen in First-Line Metastatic Upper GI Cancers

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- Domvanalimab is the only anti-TIGIT antibody in Phase 3 for upper gastrointestinal (GI) adenocarcinomas with the potential to be first-to-market for this patient population

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for people with cancer, today announced the completion of patient enrollment for STAR-221, a Phase 3 study in collaboration with Gilead Sciences, evaluating the combination of the Fc-silent anti-TIGIT antibody domvanalimab plus the anti-PD-1 monoclonal antibody zimberelimab and chemotherapy in patients with locally advanced unresectable or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma.

“STAR-221 completed enrollment well ahead of schedule, driven by significant interest from the global medical community in the potential for an anti-TIGIT-based regimen to address the high unmet need in this setting,” said Dimitry S.A. Nuyten, M.D., Ph.D., chief medical officer of Arcus Biosciences. “Domvanalimab is the first and only anti-TIGIT antibody to be studied in a Phase 3 trial in upper gastrointestinal adenocarcinoma. We are now preparing for the readout and look forward to the potential opportunity to make a meaningful difference for patients with this disease.”

Earlier this month at the American Society of Clinical Oncology (ASCO) Annual Meeting, Arcus and Gilead presented results from Arm A1 of the Phase 2 EDGE-Gastric study evaluating the same regimen in the same setting as the STAR-221 Phase 3 study. Data from this arm of EDGE-Gastric showed that patients treated with domvanalimab plus

zimberelimab and chemotherapy had a median progression-free survival (PFS) of 12.9 months, which exceeds the historical benchmarks for anti-PD-1 plus chemotherapy alone. Notably, nearly 60% of patients in the EDGE-Gastric study achieved PFS at 12 months, and the domvanalimab plus zimberelimab and chemotherapy regimen demonstrated sustained improvement across efficacy measures, including in those patients who have low PD-L1 expression. No unexpected safety signals were observed at the time of data cutoff, March 12, 2024. The domvanalimab plus zimberelimab and chemotherapy regimen was generally well tolerated and showed an overall safety profile consistent with the known safety profiles of each individual molecule to date.

Domvanalimab and zimberelimab 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 gastrointestinal cancers have not been established.

## About the STAR-221 Study

The ongoing, global STAR-221 trial (NCT05568095) enrolled approximately 1,050 participants with locally advanced unresectable or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma. The primary endpoints of the study are overall survival in PD-L1-high tumors and in the intent-to-treat population (all PD-L1 levels); secondary endpoints include progression-free survival, objective response rate and duration of response. Participants were randomized 1:1 between two arms:

- 1600 mg of domvanalimab intravenously (IV) every four weeks plus 480 mg of zimberelimab IV every four weeks plus FOLFOX (oxaliplatin, leucovorin, fluorouracil) every two weeks or 1200 mg of domvanalimab plus 360 mg of zimberelimab every three weeks plus CAPOX (capecitabine and oxaliplatin) every three weeks
- 240 mg of nivolumab IV every two weeks plus FOLFOX every two weeks or 360 mg of nivolumab plus CAPOX every three weeks

## About Domvanalimab

Domvanalimab is the first and most clinically advanced Fc-silent investigational monoclonal antibody that is specifically designed with Fc-silent properties to block and bind to the T-cell immunoreceptor with Ig and ITIM domains (TIGIT), a checkpoint receptor on immune cells that acts as a brake on the anticancer immune response. By binding to TIGIT with Fc-silent properties, domvanalimab is believed to work by freeing up immune-activating pathways and activate immune cells to attack and kill cancer cells without depleting the peripheral regulatory T cells important in avoiding immune-related toxicity.

Combined inhibition of both TIGIT and programmed cell death protein-1 (PD-1) is believed to significantly enhance immune cell activation, as these checkpoint receptors play distinct, complementary roles in anti-tumor activity.

Domvanalimab is being evaluated in combination with anti-PD-1 monoclonal antibodies, including zimberelimab, as well as other investigational cancer immunotherapies and A2a/A2b adenosine receptor antagonist etrumadenant, in multiple ongoing and planned early and late-stage clinical studies in various tumor types.

## 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. Zimberelimab has demonstrated high affinity, selectivity and potency in various tumor types.

Zimberelimab is being evaluated in the U.S. and globally as a foundational anti-PD-1 treatment option in multiple ongoing and planned early and late-stage clinical studies in combination with other immunotherapies, including investigational Fc-silent anti-TIGIT monoclonal antibody domvanalimab and A2a/A2b adenosine receptor antagonist etrumadenant.

Guangzhou Gloria Biosciences Co. Ltd., which holds commercialization rights for zimberelimab in greater China, has obtained approval for zimberelimab for the treatment of recurrent or metastatic cervical cancer and for relapsed or refractory classical Hodgkin's lymphoma. 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**.

## 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 in Dr. Nuyten's quote and statements regarding the potential for domvanalimab to be first anti-TIGIT to market for upper GI cancers. All forward-looking statements involve known and unknown risks and uncertainties and other important factors that may cause Arcus's 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 risks associated with: interim data not being replicated in future studies evaluating the same investigational molecules or regimen; the unexpected emergence of adverse events or other undesirable side effects in Arcus's investigational products, including domvanalimab and zimberelimab; risks associated with the manufacturing or supplying product for such clinical trials; uncertainties in timelines associated with the conduct of clinical studies and with respect to the regulatory application process; Arcus's dependence on the collaboration with Gilead for the successful development and commercialization of its optioned molecules; difficulties associated with the management of the collaboration activities with our strategic partners or expanded clinical programs; changes in the competitive landscape for Arcus's programs; and the inherent uncertainty associated with pharmaceutical product development and clinical trials. Risks and uncertainties facing Arcus are described more fully in the "Risk Factors" section of Arcus's most recent periodic report 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 except to the extent required by law.



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