NEWS RELEASE

Arcus Biosciences' Quemliclustat Receives Orphan Drug Designation for Pancreatic Cancer

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PRISM-1, the ongoing registrational, Phase 3 study evaluating quemliclustat plus chemotherapy as a first-line treatment for metastatic pancreatic cancer, is expected to be fully enrolled by the end of this year.

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for patients with cancer, today announced that quemliclustat, an investigational small molecule CD73 inhibitor, was granted orphan drug designation by the U.S. Food and Drug Administration for the treatment of pancreatic cancer.

"The orphan drug designation indicates the importance of developing new treatment options for rare diseases like pancreatic cancer, which has the highest mortality rate of all major cancers, and which has seen few treatment advancements over the past 30 years," said Richard Markus, M.D., Ph.D., chief medical officer at Arcus Biosciences. "We expect the Phase 3 PRISM-1 study to be fully enrolled this year and, if positive, intend to quickly bring this new first-line treatment option to patients, with the goal of prolonging survival for those with metastatic pancreatic cancer."

Orphan drug designation is intended to support the development and evaluation of new treatments for rare diseases affecting fewer than 200,000 people in the United States. Orphan drug designation qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees including New Drug Application (NDA), and a potential seven years of market exclusivity after approval.

In January 2024, Arcus presented results from the Phase 1 ARC-8 study, which showed no new safety signals and

median overall survival (OS) of 15.7 months in a pooled analysis of all patients treated with the 100mg quemliclustat-based regimens. The median OS exceeded the historical benchmark data for chemotherapy alone, including for patients with liver metastasis, which account for more than half of all pancreatic cancers. Based on the ARC-8 results, the company initiated PRISM-1, a registrational Phase 3 study to evaluate quemliclustat plus gemcitabine/nab-paclitaxel chemotherapy versus gemcitabine/nab-paclitaxel chemotherapy alone in approximately 610 patients with pancreatic ductal adenocarcinoma (PDAC) that have not been previously treated in the metastatic setting. The study is expected to be fully enrolled this year.

Quemliclustat is an investigational molecule. Approval from any regulatory authority for its use has not been received, and its safety and efficacy have not been established.

About the Phase 3 PRISM-1 Trial

PRISM-1 is a global, randomized, double-blind, placebo-controlled, multi-center Phase 3 study that will enroll approximately 610 patients with treatment-naïve metastatic PDAC. Participants will be randomized 2:1 between quemliclustat plus gemcitabine/nab-paclitaxel chemotherapy and gemcitabine/nab-paclitaxel chemotherapy plus placebo arms. The primary endpoint is overall survival (OS), and secondary endpoints include progression-free survival (PFS), objective response rate (ORR), duration of response (DOR), disease control rate (DCR) and safety.

About Quemliclustat

Quemliclustat is an investigational, potent and selective small molecule CD73 inhibitor that is being co-developed in collaboration with Gilead Sciences. CD73 is the primary enzymatic producer of immunosuppressive adenosine in the tumor microenvironment, and high CD73 expression is associated with significantly poorer prognosis in several tumor types. Quemliclustat has been shown to block the production of adenosine. Once the immunosuppressive effects of adenosine are removed, activation of antitumor immune cells may be restored, resulting in cancer cell death.

About Pancreatic Cancer

According to the American Cancer Society, approximately 67,440 Americans will be diagnosed with pancreatic cancer in the U.S. in 2025, and pancreatic cancer has the highest mortality rate of all major cancers. Approximately 50% of people with PDAC are diagnosed in the metastatic setting, which is associated with a five-year survival rate of only 3%. Pancreatic cancer occurs in the pancreas, an organ located behind the stomach that helps with digestion and controlling blood sugar. The majority (over 90%) of pancreatic cancers are adenocarcinomas, a type of cancer that forms in tissues that line certain internal organs and release fluids like those that help with digestion. There have been limited advancements for treating pancreatic cancer, and chemotherapy has been the standard of

care for more than 30 years.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company developing differentiated molecules and combination therapies 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 advanced multiple investigational medicines into registrational clinical trials including domvanalimab, an Fc-silent anti-TIGIT antibody being studied in combination with zimberelimab, an anti-PD-1 antibody, for upper gastrointestinal and non-small cell lung cancer, casdatifan, a HIF-2a inhibitor for clear cell renal cell carcinoma, and quemliclustat, a small-molecule CD73 inhibitor for pancreatic cancer. For more information about Arcus Biosciences' clinical and preclinical programs, please visit **www.arcusbio.com**.

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. Markus' quote and statements regarding: the timing for completing enrollment of PRISM-1; and the potency, efficacy or safety of Arcus's investigational products, including quemliclustat. 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 preliminary and interim data not being guarantees that future data will be similar; the unexpected emergence of adverse events or other undesirable side effects; difficulties or delays in initiating or conducting clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; 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 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 Quarterly Report on Form 10-Q 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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