

NEWS RELEASE

Arcus Biosciences Retains Rights to Casdatifan, a Potential Best-in-Class HIF-2a Inhibitor, and Announces Pricing of \$150 Million Common Stock Offering

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- Gilead Sciences' window to exercise its option to casdatifan has expired; \$150 million financing enables Arcus to independently advance its development program for casdatifan
- New data from the ARC-20 study in patients with clear cell renal cell carcinoma (ccRCC) showed that casdatifan monotherapy demonstrated improvements in the rate of primary progression, overall response rate (ORR) and progression-free survival (PFS) and reinforced its differentiation relative to published data from studies with HIF-2a inhibitors to date
- Arcus will host a conference call today to discuss the ARC-20 results and casdatifan development plans at 5:00
 AM PT / 8:00 AM ET

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 Gilead's time-limited exclusive option rights to casdatifan have expired. In addition, Arcus has announced the pricing of a \$150 million common stock offering, which is subject to customary closing conditions and includes participation from new and existing institutional healthcare investors and Gilead. Today's financing is expected to fund Arcus through the anticipated data readout for PEAK-1, the Phase 3 trial for casdatifan in the immuno-oncology (IO)-experienced ccRCC setting. This financing, combined with the world class development and regulatory expertise that Arcus has already established, will enable Arcus to rapidly advance casdatifan and maintain the momentum for this program that Arcus has independently built to date.

"We are thrilled to retain ownership of casdatifan, which has the potential to address a significant unmet need for patients with an estimated \$5 billion market opportunity. Owning the rights to casdatifan represents a transformational change for Arcus, providing us with significant future strategic optionality," said Terry Rosen, Ph.D., chief executive officer of Arcus. "Data just presented in an oral presentation at the ASCO GU conference demonstrated casdatifan's potential to be the best-in-class HIF-2a inhibitor in what appears to be a two-horse race. We anticipate that every patient with ccRCC will receive a HIF-2a inhibitor, and our development plan is designed to position casdatifan as the HIF-2a inhibitor of choice. This includes the initiation of our Phase 3 PEAK-1 study in the IO-experienced setting, and our clinical collaboration with AstraZeneca with the eVOLVE study, which will combine casdatifan with their anti-PD-1/CTLA-4 bispecific in the IO-naive setting."

The new data from ARC-20, a Phase 1/1b study of the HIF-2a inhibitor casdatifan in ccRCC, were presented in a rapid oral session at the 2025 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium by Dr. Toni Choueiri, Dana-Farber Cancer Institute. The presentation included ORR for the 50mg twice-daily (BID) cohort, 50mg once-daily (QD) cohort and 100mg QD (tablet) cohort in patients who had progressed on at least two prior therapies, including both an anti-PD-1 and a VEGFR tyrosine kinase inhibitor (TKI) therapy. Arcus also reported the first median PFS data for the 50mg BID cohort.

Expected milestones for casdatifan in 2025 and 2026 are:

- <u>Q2 2025</u>: To initiate PEAK-1, which will evaluate casdatifan plus cabozantinib versus cabozantinib in the IO-experienced metastatic ccRCC setting. The primary endpoint will be PFS.
- Mid-2025: To present initial safety and efficacy data from the casdatifan plus cabozantinib cohort of ARC-20.
- Fall 2025: To share more mature results for the casdatifan monotherapy cohorts of ARC-20.
- 2025: To initiate a Phase 1b study, part of the eVOLVE portfolio, which AstraZeneca will operationalize, to evaluate casdatifan plus volrustomig, an investigational anti-PD-1/CTLA-4 bispecific antibody, in ccRCC patients who are IO-naive. This clinical collaboration enables Arcus to pursue the IO-naive setting in a capital and resource efficient manner while retaining all rights to casdatifan.
- 2026: To share initial data from newly added cohorts of ARC-20 evaluating casdatifan monotherapy in favorable risk first-line (1L) ccRCC, casdatifan plus zimberelimab in 1L ccRCC and casdatifan monotherapy in IO-experienced/TKI-naive ccRCC.

Investors may dial in to the conference call at +1 404 975 4839 (local) or +1 833 470 1428 (toll-free) using Conference ID: 331780 today, Tuesday, February 18, 2025 at 5:00 AM PT / 8:00 AM ET. Participants may also register for the call online using the following link: https://events.q4inc.com/attendee/364282703. To access the live webcast and accompanying slide presentation, please visit the "Investors & Media" section of the Arcus Biosciences website at www.arcusbio.com. A replay will be available following the live event.

About RCC

According to the American Cancer Society, kidney cancer is among the top 10 most commonly diagnosed forms of cancer among both men and women in the U.S., and an estimated 80,980 Americans will be diagnosed with kidney cancer in 2025. Clear cell RCC is the most common type of kidney cancer in adults. If detected in its early stages, the five-year survival rate for RCC is high; for patients with advanced or late-stage metastatic RCC, however, the five-year survival rate is only 18%. In 2022, approximately 32,200 patients with advanced kidney cancer required systemic therapy in the U.S., with over 20,000 patients receiving first-line treatment.

About Casdatifan (AB521)

Casdatifan is a small-molecule inhibitor of HIF-2a, a transcription factor responsible for activating multiple tumor growth pathways in hypoxic and pseudo-hypoxic tumor environments. By selectively binding HIF-2 α , casdatifan is designed to shut down hypoxic oncogenesis, which blocks tumor growth and key oncogenic pathways, leading to cancer cell death. Clear cell RCC (ccRCC) is almost universally associated with HIF-2a dysregulation. Casdatifan is currently being evaluated in ARC-20, a Phase 1/1b study in renal cell carcinoma and other cancers.

Casdatifan 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 Gilead Collaboration

In May 2020, Arcus established a 10-year collaboration with Gilead to strategically advance our portfolio. Under this collaboration, Gilead obtained time-limited exclusive option rights to all of our clinical programs arising during the collaboration term. Arcus and Gilead are co-developing four investigational products, including zimberelimab (Arcus's anti-PD-1 molecule), domvanalimab (Arcus's anti-TIGIT antibody), etrumadenant (Arcus's adenosine receptor antagonist) and quemliclustat (Arcus's CD73 inhibitor). The collaboration was expanded in November 2021 and May 2023 to include research directed to two targets for oncology and two targets for inflammatory diseases.

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, HIF-

2a, CD73, dual A2a/A2b receptor, CD39, and AXL. 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 regarding the initiation, design of and associated timing for future studies, including statements about PEAK-1 and the eVOLVE study; the potential market opportunity for casdatifan; plans to disclose or present study analyses or data, including any analyses or data from ARC-20; whether data and results from studies validate our pipeline or support further development of a program; the potency, efficacy or safety of Arcus's investigational products, including their potential for a best-in-class profile; the expected closing of the common stock offering and the expected participation in the offering from certain investors; and Arcus's expectation that the common stock offering positions Arcus to fund its operations through the anticipated data readout for PEAK-1. 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 in Arcus's investigational products; 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; unfavorable global economic, political and trade conditions; Arcus's dependence on the collaboration with third parties such as Gilead and Taiho 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 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 forwardlooking statements contained in this press release except to the extent required by law.

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