NEWS RELEASE

Arcus Outlines 2026 Plans for Casdatifan, its Potential Best-in-Class HIF-2a Inhibitor, and its Inflammation Programs

2026-01-07

- Arcus's highest priority is to execute on its ongoing Phase 3 trial and overall development plan aimed at establishing casdatifan as the standard-of-care and backbone therapy for clear cell renal cell carcinoma (ccRCC), including the initiation of a Phase 3 trial in the first-line (1L) setting
- At least three data presentations are planned for casdatifan in 2026, including updated data from the four late-line monotherapy cohorts of the Phase 1/1b ARC-20 study, which will be presented at a medical conference in February 2026
- Arcus's first development candidate for inflammatory and autoimmune diseases, an oral MRGPRX2 antagonist for chronic spontaneous urticaria, is expected to enter the clinic in 2026
- With approximately $1 billion of cash and investmentsi, Arcus expects to be able to fund its planned operations until at least the second half of 2028
- Arcus will present at the 44th Annual J.P. Morgan Healthcare Conference on Wednesday, January 14, 2026

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules for patients with cancer and inflammatory and autoimmune diseases, today outlined its 2026 priorities for casdatifan and its emerging inflammation and immunology (I&I) programs.

"As we enter 2026, the highest priorities for Arcus will be the rapid enrollment of PEAK-1, our Phase 3 study evaluating casdatifan in immunotherapy (IO)-experienced ccRCC patients, and the initiation of a 1L Phase 3 study evaluating casdatifan informed by data from multiple ongoing and soon-to-be initiated Phase 1 combination

studies," said Terry Rosen, Ph.D., chief executive officer of Arcus. "This year, we also expect to advance our first small molecule for inflammatory disease into the clinic."

Casdatifan (HIF-2a inhibitor for ccRCC)

Upcoming Data Presentations:

Arcus expects to have at least three data readouts for casdatifan, its potential best-in-class HIF-2a inhibitor, during 2026:

- In February 2026, Arcus plans to present updated data from the four cohorts of the Phase 1/1b ARC-20 study evaluating casdatifan monotherapy in late-line ccRCC at a medical conference. These data will include updated progression-free survival (PFS) data for the 100mg once-daily (QD) cohort of casdatifan and for all four monotherapy cohorts combined (n=121), as well as updated biomarker data correlating erythropoietin suppression with clinical outcomes.
- Mid-year, Arcus expects to present updated data for approximately 45 patients treated in ARC-20 with casdatifan plus cabozantinib in IO-experienced ccRCC; this cohort evaluates the same combination in the same setting as PEAK-1, an ongoing Phase 3 study, which represents Arcus's "fast-to-market" strategy in ccRCC.
- In the second half of the year, Arcus expects to present data from multiple ARC-20 cohorts evaluating casdatifan in early-line metastatic settings, including data from the cohort evaluating casdatifan plus the anti-PD-1 antibody, zimberelimab, in 1L ccRCC.
    - This will be the first presentation of data for a tyrosine kinase inhibitor (TKI)-sparing HIF-2a inhibitor-based regimen in the 1L setting. Data from this cohort are expected to show an acceptable safety profile and early efficacy, including a low rate of primary progression, which is essential in this setting. The cohort is designed to de-risk Arcus's strategy to displace TKIs as an early-line treatment.

Development Strategy:

Arcus's development plan is designed to establish casdatifan as a foundational standard of care across multiple settings of ccRCC, which represents a potential global market opportunity of $5 billion or more.

Arcus's ongoing Phase 3 study for casdatifan in IO-experienced ccRCC, PEAK-1, is evaluating casdatifan plus cabozantinib, the most widely used TKI in this setting. Similar Phase 3 trials in this setting have completed enrollment in 18 months or less, and Arcus's goal is to achieve a similar timeline.

Arcus's strategy in 1L ccRCC is focused on TKI-free regimens, which are enabled by the consistently low rate of primary progression observed with casdatifan across all cohorts and settings evaluated to date. This strategy has

the potential to bring about a highly desirable paradigm shift with a first-in-class regimen that delays treatment with TKIs and their associated toxicities to later lines of therapy. The following cohorts are designed to efficiently determine the optimal 1L registrational strategy for casdatifan:

- Casdatifan plus zimberelimab (Arcus's anti-PD-1 antibody): This combination is currently being evaluated in ARC-20, and this cohort has completed enrollment. Arcus plans to present data from this cohort in the second half of 2026.
- Casdatifan plus anti-PD-1-containing regimens: Arcus is planning to initiate new cohorts to evaluate two other TKI-free casdatifan plus anti-PD-1-containing regimens in the 1L setting.
- Casdatifan plus volrustomig (AstraZeneca's anti-PD-1/CTLA-4 bispecific antibody): This combination is being evaluated in the eVOLVE-RCC02 study (which is being operationalized by AstraZeneca).

Data from these cohorts will inform and enable the initiation of a Phase 3 study for a casdatifan-containing, TKI-free regimen in the 1L setting. Arcus is targeting initiation of this study by year-end 2026.

Small-Molecule Inflammation & Immunology Programs

- Arcus's I&I strategy leverages the company's demonstrated capabilities in small-molecule drug discovery, focusing on indications currently dominated by blockbuster injectable biologics and on highly validated targets. Arcus's I&I portfolio currently includes several oral small molecules, including an MRGPRX2 antagonist and inhibitors of TNF, CCR6 and CD40L. The company is also developing an anti-CD89 antibody that has potential in patients with a type of rheumatoid arthritis that is currently difficult to treat.
- Arcus expects to advance its lead inflammation program, a potential best-in-class oral MRGPRX2 antagonist for atopic dermatitis and chronic spontaneous urticaria, into clinical development in 2026. The molecule was designed to have exquisite potency, enabling substantially lower-dose target coverage relative to the most advanced MRGPRX2 antagonist in clinical development, thereby avoiding potential exposure-limiting toxicities.
- Arcus also expects to advance an oral small-molecule TNF inhibitor, a potential treatment for rheumatoid arthritis, psoriasis and inflammatory bowel disease (such as ulcerative colitis), into the clinic in late 2026 or early 2027.

Quemliclustat (CD73 inhibitor for pancreatic cancer)

- Arcus's oncology portfolio also includes quemliclustat, a small-molecule CD73 inhibitor, which is being evaluated in PRISM-1, a registrational Phase 3 study in 1L pancreatic cancer that completed enrollment in September 2025. Results from this study are expected in the first half of 2027.

Runway Guidance

Arcus has approximately $1 billion of cash and investmentsi and expects to be able to fund its planned operations until at least the second half of 2028. This guidance includes a rapid wind down of the Phase 3 STAR-221 and Phase 2 EDGE-GASTRIC studies. In the first quarter of 2026, Arcus and Gilead expect to conduct an analysis of STAR-121, a Phase 3 study evaluating domvanalimab plus zimberelimab and chemotherapy in 1L non-small cell lung cancer. Depending on the outcome of this analysis, Arcus could realize additional cost savings.

Presentation at 44th Annual J.P. Morgan Healthcare Conference

Arcus will present at the 44th Annual J.P. Morgan Healthcare Conference at 3:00 pm PT on Wednesday, January 14, 2026. A live webcast of the presentation will be available on the “Investors & Media” section of the Arcus Biosciences website at **www.arcusbio.com**. A replay will be available following the live event.

Domvanalimab, zimberelimab and quemliclustat are investigational molecules, and neither Arcus nor Gilead has received approval from any regulatory authority for any use globally, and their safety and efficacy have not been established. Casdatifan is also an investigational molecule, and Arcus has not received approval from any regulatory authority for any use globally, and its safety and efficacy have not been established.

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 master switch that turns on hundreds of genes in response to low oxygen levels. In a majority of people with the most common form of kidney cancer (clear cell renal cell carcinoma), genetic anomalies result in the dysregulation of this master switch and transformation of normal kidney cells into cancerous ones. Casdatifan was designed to provide deep and durable inhibition of the HIF-2a pathway. Early clinical studies have shown high response rates and a low primary progression rate relative to clinical benchmarks, warranting further investigation in late-stage studies. Casdatifan, which is administered in pill form once daily, has a safety profile that allows it to be investigated in combination with other treatments.

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 clinical studies in combination with other immunotherapies. 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 focused on developing differentiated molecules for the treatment of cancer and inflammatory and autoimmune diseases. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of its late-stage portfolio of first- and/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 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 Statement

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, Arcus's goals and strategy for its casdatifan and inflammation and immunology programs; the potential for casdatifan to become a standard-of-care or "backbone" therapy or to be best-in-class; planned, expected or potential timing, occurrence and content of clinical data readouts, presentations and publications (including those from ARC-20, eVOLVE-RCC02, PEAK-1 and PRISM-1); the design, initiation, enrollment, conduct and timelines of ongoing or planned clinical trials (including the potential initiation of a 1L Phase 3 study by year-end 2026 and enrollment goals for PEAK-1); the anticipated clinical profile of Arcus's product candidates, including safety, tolerability and activity, and expectations regarding TKI-sparing regimens; the advancement and

therapeutic potential of Arcus's I&I candidates (including MRGPRX2 antagonist and TNF inhibitor) and the timing of their entry into the clinic; the scope and timing of program wind-downs; market opportunity estimates; collaboration activities and expectations (including with AstraZeneca and Gilead); and Arcus's cash runway and other financial or operational expectations. 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: the outcomes of anticipated analyses from ongoing Phase 3 studies with domvanalimab, including STAR-121 and PACIFIC-8; delays in the wind-down of STAR-221 and EDGE-Gastric; the unexpected emergence of adverse events or other undesirable side effects in Arcus's investigational products, including casdatifan; risks associated with preliminary and interim data not being guarantees that future data will be similar; 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; further changes to Arcus's strategy and operating plans; changes in the competitive landscape for Arcus's programs; reliance on collaborators and third parties (including AstraZeneca and Gilead) and related dependencies; regulatory feedback that may alter design or timing; and assumptions underlying cash-runway guidance and program wind-downs 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.

i Based on cash, cash equivalents and marketable securities balance of $841 million as of September 30, 2025, and net proceeds of approximately $270 million from Arcus's November 2025 financing.

Investor Inquiries:

Pia Eaves
VP of Investor Relations & Strategy
(617) 459-2006
peaves@arcusbio.com

Media Inquiries:

Holli Kolkey
VP of Corporate Affairs
(650) 922-1269
hkolkey@arcusbio.com

Maryam Bassiri
AD, Corporate Communications
(510) 406-8520
mbassiri@arcusbio.com

Source: Arcus Biosciences