NEWS RELEASE

Arcus Presents New Data for its HIF-2a Inhibitor Casdatifan, Which Showed Progression-Free Survival Beyond One Year in Late-Line Kidney Cancer

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- Median progression-free survival (mPFS) was 15.1 months, and the confirmed overall response rate (cORR) increased to 45% for the 100mg QD (once daily) tablet cohort in an updated analysis of the ARC-20 study
- In a pooled analysis of all four monotherapy cohorts (n=121), casdatifan data were better on every efficacy measure evaluated relative to published data from studies with the only marketed HIF-2a inhibitor
- New biomarker data demonstrated correlation between magnitude and durability of serum erythropoietin (sEPO) suppression by casdatifan and clinical benefit, including cORR and PFS

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 announced a new analysis of efficacy and biomarker data for casdatifan, a HIF-2a inhibitor with best-in-class potential, in late-line metastatic clear cell renal cell carcinoma (ccRCC) from the Phase 1/1b ARC-20 study. These data will be presented in a poster session on February 28, 2026, at the American Society of Clinical Oncology Genitourinary Cancer Symposium.

“Patients in the 100mg tablet cohort reached 15.1 months of PFS, and 45% had a confirmed response when treated with the same dose and formulation being used in the ongoing Phase 3 study,” said Richard Markus, M.D., Ph.D., chief medical officer at Arcus Biosciences. “With longer follow-up, ORR continued to improve for both the 100mg QD cohort and pooled analysis, increasing meaningfully since the last analysis. Whether evaluating the pooled data or 100mg Phase 3 formulation data, PFS was two or nearly three times longer relative to published data from studies

with the only marketed HIF-2a inhibitor in the same patient population."

ARC-20 is a Phase 1/1b dose-escalation and expansion study that included four monotherapy cohorts (n=121), which evaluated casdatifan in patients with metastatic ccRCC, most of whom had progressed on at least two prior lines of therapy, including both an anti-PD-1 and a VEGFR tyrosine kinase inhibitor (TKI): 50mg twice daily (BID), 50mg QD, 100mg QD (tablet) and 150mg QD. For biomarker analysis, serial serum samples were collected, and associations between maximal sEPO reduction and response to casdatifan were evaluated. These data showed that the magnitude and durability of EPO suppression correlated with clinical benefit, thereby linking pharmacodynamic modulation by casdatifan to clinical efficacy, including ORR and PFS.

"An analysis of data for casdatifan, a next-generation HIF-2a inhibitor, showed the majority of patients reached near-maximal sEPO reduction, and that deep and prolonged suppression was associated with better response and clinical benefit," said Toni K. Choueiri, M.D., director of the Lank Center for Genitourinary (GU) Oncology at Dana-Farber, the Jerome and Nancy Kohlberg chair and professor of medicine at Harvard Medical School, and lead investigator of ARC-20. "HIF-2a inhibition has emerged as a novel treatment that is changing the treatment paradigm for patients with ccRCC, and the results from ARC-20 are very encouraging. I look forward to working with Arcus to bring this medicine to ccRCC patients as soon as possible."

At the time of data cut-off (DCO, August 15, 2025), no unexpected safety signals were observed, and casdatifan had an acceptable and manageable safety profile across all doses. Across all four cohorts, no patients discontinued treatment due to anemia, and four patients (3%) discontinued due to hypoxia.

	100mg QD Tablet (Phase 3 dose) (n=32)	Pooled Analysis (50mg BID, 50mg QD, 100mg QD, 150mg QD) (n=127)
Safetya		
Any Serious Treatment-Emergent Adverse Events (TEAEs)	31% (10)	31% (39)
Grade ≥3 TEAEs related to casdatifanb		
Anemia	25% (8)	41% (52)
Hypoxia	9% (3)	11% (14)
TEAEs resulting in discontinuation	9% (3)	9% (11)
Anemiac	0	0
Hypoxiac	3% (1)	2% (3)

a The safety-evaluable population included all dose-expansion enrolled patients who received any amount of any study treatment.
b Grade ≥3 TEAEs related to casdatifan that occurred in more than 5% of patients in the pooled analysis.
c Prespecified events of interest.

An updated analysis was conducted for efficacy with a DCO of January 30, 2026. The safety profile remained consistent with the August 15, 2025 DCO. Key differences between the August 15, 2025 and January 30, 2026 DCO are as follows:

- 100mg QD tablet cohort: At 17.9 months of median follow-up, cORR increased to 45% with an mPFS of 15.1 months. An mPFS had not yet been reached, and cORR was 35% at the August 15, 2025 DCO.
- Pooled analysis: At 20.8 months of median follow-up, cORR increased to 35%, with three of the four monotherapy cohorts having cORRs greater than 30%, and mPFS was stable at 12.2 months; cORR was 31% at the August 15, 2025 DCO.

	100mg QD Tablet (Phase 3 dose) (n=31)	Pooled Analysis (50mg BID, 50mg QD, 100mg QD, 150mg QD) (n=121)
Efficacya		
Median Follow-Up	17.9 months	20.8 months
Median PFS [95% CI]	15.1 months [5.7,NE]	12.2 months [9.4,16.5]
12-month PFS [95% CI]	61% [42,76]	51% [41,60]
6-month PFS [95% CI]	68% [48,81]	63% [54,71]
Confirmed ORR (cORR) [95% CI]	45% (14) [27,64]	35% (42) [26,44]
Confirmed BOR		
CR	0	1% (1)
PR	45% (14)	34% (41)
SD	39% (12)	46% (56)
PDb,c	16% (5)	19% (23)
Median Time to Response	2.6 months	2.8 months
Disease Control Rate [95% CI]	84% (26) [66,95]	81% (98) [73,88]

BOR: best overall response; CI: confidence interval; CR: complete response; NE: not estimable; PR: partial response; PD: progressive disease; SD: stable disease

a As of DCO of January 30, 2026; efficacy-evaluable population for this expansion cohort is defined as all eligible participants who received any study treatment and have at least one post-baseline efficacy assessment, or discontinued study treatment due to progressive disease or death.

b PD was defined according to RECIST v1.1 as a ≥ 20% increase in the sum of diameters of target lesions relative to the smallest sum on study (including baseline, if smallest), with an absolute increase of ≥ 5 mm. The appearance of 1 or more new lesions was also considered progression.

c Includes two patients in the 100mg QD tablet cohort, and also included in the pooled analysis, who had clinical progression before the first scan and therefore did not meet criteria for progressive disease per RECIST. PD based on RECIST criteria was 10% (n=3) for the 100mg QD tablet cohort and 17% (n=121).

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.

Currently, fewer than one in four patients with late-line ccRCC respond to monotherapy treatment with a HIF-2a inhibitor, and a next-generation option, like casdatifan, may help more patients achieve benefit from HIF-2a-inhibitor treatment.

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. Taiho has development and commercial rights in Japan and other countries in Asia, excluding China. Arcus Biosciences holds full rights to casdatifan everywhere else globally.

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 80,450 Americans will be diagnosed with kidney cancer in 2026. 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 kidney cancer is high; for patients with advanced or late-stage metastatic kidney cancer, however, the five-year survival rate is only 19%. For metastatic kidney cancer, targeted drug therapies are one of the main treatment options.

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**.

Important Information Regarding Data Comparisons

This press release includes comparisons between data from our Phase 1/1b ARC-20 trial and published data from separate trials that are not head-to-head studies. Cross-trial comparisons should be interpreted with caution due to differences in study populations, sample sizes, inclusion and exclusion criteria, trial design, and other factors that may limit direct comparability.

Important Information Regarding 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, casdatifan as a next generation HIF-2a inhibitor. 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 materially 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 a guarantee of future data and may not be replicated in other studies evaluating casdatifan, including the Phase 3 PEAK-1 study; the unexpected emergence of adverse events or other undesirable side effects with casdatifan; risks associated with manufacturing or supplying product for clinical trials evaluating casdatifan; 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 (SEC) and in other filings that Arcus makes with the SEC from time to time, which are available at **www.sec.gov**. You are cautioned not to place undue reliance on these 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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