



## NEWS RELEASE

# Arcus Biosciences to Present New Data from Casdatifan, a HIF-2a Inhibitor, in an Oral Presentation at the 2025 ASCO GU Symposium

2025-02-10

- New data from ARC-20, a Phase 1/1b study of the HIF-2a inhibitor casdatifan in clear cell renal cell carcinoma (ccRCC), will be presented in a rapid oral session by Dr. Toni Choueiri, Dana-Farber Cancer Institute
- The presentation will include initial data from the 100mg once-daily (QD) tablet cohort and updated data for the 50mg twice-daily (BID) and 50mg QD cohorts
- Arcus will host a conference call to discuss the ARC-20 data at 5:00 AM PT / 8:00 AM ET on Tuesday, February 18, 2025

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 data from the ARC-20 study will be presented in a rapid oral session at the 2025 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium taking place February 13 – 15, 2025, in San Francisco, CA.

The oral presentation will highlight safety and efficacy data from three cohorts of ARC-20, which evaluated casdatifan monotherapy in patients that had received both prior TKI and anti-PD-1 therapy. The presentation will include initial data for the 100mg QD tablet cohort, our selected dose and formulation for Arcus's Phase 3 studies, as well as updated data for the 50mg BID and 50mg QD expansion cohorts of ARC-20.

"We look forward to presenting new data from our ARC-20 study evaluating our HIF-2a inhibitor, casdatifan, in an

oral presentation at ASCO GU,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “The data to be shared support the differentiation of casdatifan, across all key efficacy measures, relative to published data from studies with HIF-2a inhibitors. We are continuing to rapidly advance an extensive and robust development program for casdatifan, including the planned initiation of our first Phase 3 study (PEAK-1) in the first half of this year, a clinical collaboration with AstraZeneca to evaluate casdatifan in combination with volrustomig and the addition of new cohorts to ARC-20 to evaluate casdatifan in the first-line setting. We also look forward to presenting additional data from ARC-20 throughout the year.”

Study	Title	Abstract Number	Session Type & Title	Session Date & Time
Casdatifan (HIF-2a Inhibitor)				
ARC-20	Casdatifan (Cas) Monotherapy in Patients (pts) with Previously Treated Clear Cell Renal Cell Carcinoma (ccRCC): Safety, Efficacy and Subgroup Analysis Across Multiple Doses from ARC-20, a Phase 1 Open-Label Study	441	Rapid Oral Abstract Session C: Renal Cell Cancer and Penile Cancer	2/15/2025 12:45 PM - 12:50 PM PT

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 on 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](http://www.arcusbio.com). A replay will be available following the live event.

## 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-2a, 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 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 81,600 Americans will be diagnosed with kidney cancer in 2024. 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 15%. 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 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, A2a/A2b receptors, CD39 and AXL. For more information about Arcus Biosciences's clinical and preclinical programs, please visit [www.arcusbio.com](http://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. Rosen's quote and statements regarding: the potency, efficacy or safety of casdatifan; how data from ARC-20 will support or advance Arcus's development program for casdatifan, including plans for future development; plans and timing to initiate new studies or cohorts; and combinations that Arcus plans to explore in future studies. 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 forward-looking statements contained in this press release except to the extent required by law.

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Source: Arcus Biosciences