



NEWS RELEASE

Arcus Biosciences Announces Clinical Supply Agreement with AVEO Oncology to Evaluate Casdatifan in Combination with Tivozanib for Advanced Kidney Cancer Patients

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- This agreement supports a new randomized cohort within the ARC-20 study evaluating investigational casdatifan plus tivozanib versus tivozanib alone in patients who received prior HIF-2 α -inhibitor therapy
- Enrollment is expected to begin in the fourth quarter of 2026

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE: RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for people with cancer and inflammatory and autoimmune diseases, today announced a clinical supply agreement with AVEO Oncology, an LG Chem company ("AVEO"). Under the agreement, the companies will evaluate casdatifan, Arcus's investigational small-molecule HIF-2 α inhibitor, in combination with tivozanib (FOTIVDA®), AVEO's vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI), in a new randomized cohort within ARC-20, Arcus's platform study of casdatifan in patients with advanced clear cell renal cell carcinoma (ccRCC).

The new cohort in ARC-20 will evaluate casdatifan in combination with the recommended dose of tivozanib (1.34 mg) compared to tivozanib (1.34 mg) alone in patients with advanced ccRCC who received prior HIF-2 α -inhibitor therapy. ARC-20 is a platform study evaluating casdatifan across multiple cohorts in metastatic ccRCC alone or in combination with other potential treatment options. Under the terms of the agreement, AVEO will supply tivozanib, and Arcus will conduct and sponsor the combination study. Each company will retain development and commercial rights to its respective compounds.

“HIF-2α inhibition is emerging as an important standard of care in kidney cancer, and we believe that casdatifan, with its demonstrated pharmacokinetic/pharmacodynamic advantages, may extend benefit for patients who have progressed on a first-generation HIF-2α inhibitor,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “This collaboration with AVEO, combining casdatifan with tivozanib, a VEGFR TKI with an established, distinct safety profile, will further our intent to establish casdatifan as a therapy that can benefit every patient across each line of therapy, and clarify the potential efficacy that casdatifan can bring in patients previously treated with a HIF-2α inhibitor-inclusive regimen.”

This investigational therapy will be part of a holistic development strategy that is intended to provide physicians and patients with: 1) a casdatifan-based TKI-sparing first-line treatment; 2) a casdatifan-based TKI-inclusive first-line regimen; 3) a second-line HIF-2α-inhibitor treatment that builds on the second-line standard-of-care TKI, cabozantinib; and 4) a combination with a highly selective TKI therapy that can also provide benefit to patients previously treated with a HIF-2α inhibitor-based therapy.

About Casdatifan (AB521)

Casdatifan is a small-molecule inhibitor of hypoxia-inducible factor 2-alpha (HIF-2α), 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-2α pathway. Early clinical studies have shown high response rates and a low primary progression rate relative to clinical benchmarks, warranting further investigation in patients that have progressed on therapies inclusive of a HIF-2α inhibitor. Casdatifan, which is administered in pill form once daily, has a safety profile that allows it to be investigated in combination with other treatments.

The casdatifan development strategy is designed to generate evidence needed to establish casdatifan as a backbone therapy so that every patient has the opportunity to benefit from casdatifan across each line of therapy. In addition to partner-operationalized studies, Arcus is investigating casdatifan across multiple cohorts in the ARC-20 platform study, alone and in combination with other potential new treatment options, including in:

- The first-line setting with cohorts evaluating casdatifan plus zimberelimab, an anti-PD-1 (ongoing); casdatifan plus zimberelimab and ipilimumab, an anti-CTLA-4 (ongoing); and casdatifan plus ivonescimab, an anti-PD-1/VEGF bispecific (planned)
- The second-line setting with a cohort evaluating casdatifan plus cabozantinib, in immunotherapy-experienced

patients (ongoing)

- A cohort evaluating casdatifan plus tivozanib, a TKI, in HIF-2 α inhibitor-experienced patients (planned)

Arcus is also enrolling PEAK-1, the global Phase 3 study evaluating casdatifan plus cabozantinib versus cabozantinib in immunotherapy-experienced metastatic ccRCC. Arcus expects to complete enrollment in PEAK-1 and to initiate a Phase 3 study in the first-line ccRCC setting by year-end 2026.

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 Tivozanib

FOTIVDA® (tivozanib) is a next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI). It was approved by the FDA in March 2021 for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.¹

References: 1. FOTIVDA (tivozanib) [package insert]. Boston, MA: AVEO Pharmaceuticals, Inc, January 2025.

About Kidney Cancer

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. ccRCC 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-2 α 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.

About AVEO Pharmaceuticals, Inc.

AVEO Pharmaceuticals, Inc., an LG Chem company, (AVEO Oncology) is an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer. AVEO currently markets FOTIVDA® (tivozanib) in the U.S. for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO and its strategic partners continue to develop FOTIVDA in other novel targeted combinations in RCC. The company also has investigational programs in other areas of high unmet need, including ficlatuzumab in HPV-negative refractory head and neck squamous cell carcinoma and rilogrotug (also known as AV-380) in cancer cachexia. AVEO became a wholly owned subsidiary of LG Chem Life Sciences USA, Inc. on January 19, 2023. AVEO continues to operate under the AVEO Oncology, an LG Chem company, name.

Arcus 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 potential for casdatifan and tivozanib to provide benefit to patients previously treated with a HIF-2 α inhibitor-based therapy, Arcus's development strategies and plans, and the timing and achievement of milestones, including enrollment of the new ARC-20 cohort beginning in the fourth quarter of 2026 and the completion of enrollment in PEAK-1 by year-end 2026. 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: managing Arcus's collaborations; risks associated with manufacturing or supplying product for clinical trials evaluating casdatifan; the unexpected emergence of adverse events or other undesirable side effects with casdatifan or casdatifan-based combinations; 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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