



NEWS RELEASE

Arcus Biosciences and Summit Therapeutics Enter Into Clinical Trial Collaboration to Evaluate Casdatifan Combined with Ivonescimab in Kidney Cancer

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Data Expected to Be Generated by Mid-2027

HAYWARD, Calif. & MIAMI--(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, and Summit Therapeutics Inc. (Nasdaq: SMMT), a biopharmaceutical company focused on patient-friendly oncology therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs, today announced a clinical trial collaboration to evaluate the safety and efficacy of Arcus's casdatifan, an investigational hypoxia-inducible factor 2-alpha (HIF-2α) inhibitor, in combination with Summit's ivonescimab, an investigational PD-1/VEGF bispecific antibody, in clear cell renal cell carcinoma (ccRCC), including first-line metastatic disease, the most common form of kidney cancer.

"Combining casdatifan, a hard-hitting HIF-2α inhibitor, with ivonescimab, the most advanced and well-studied anti-PD-1/VEGF bispecific, presents a compelling opportunity to create a well-tolerated and TKI-sparing combination that has the potential to prolong survival," said Terry Rosen, Ph.D., Chief Executive Officer of Arcus. "Our development strategy is to establish casdatifan as a backbone therapy so that every patient has the opportunity to benefit from casdatifan across each line of therapy, and this collaboration enables the evaluation of a highly innovative regimen with strong scientific and clinical rationale to be an important first-line treatment for kidney cancer."

The clinical trial collaboration will evaluate casdatifan in combination with ivonescimab in a new cohort to be added

to ARC-20, Arcus's platform study, evaluating casdatifan alone or in combination with other potential treatment options across multiple cohorts in metastatic ccRCC. Under the terms of the agreement, Summit will supply ivonescimab and Arcus will conduct and sponsor the combination study. Both companies will contribute to the cost of the study, and each company will retain development and commercial rights to their respective molecules. Initial data from this clinical trial collaboration is expected to be generated by mid-2027.

"Ivonescimab's novel mechanism of action targeting both the PD-1 axis and VEGF pathway is particularly compelling in renal cell carcinoma, where both pathways are known to play an important role in disease progression," said Dr. Maky Zanganeh, President and Co-Chief Executive Officer of Summit Therapeutics. "We are excited to get this work underway with Arcus to evaluate whether the combination of ivonescimab and casdatifan can translate into improved and more durable outcomes for patients. Despite recent advances, kidney cancer remains a disease area with stark stage-dependent survival where only a small proportion of patients survive beyond five years, highlighting the ongoing unmet need in this tumor setting."

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 2026.¹ ccRCC is the most common type of kidney cancer in adults.² 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%.³ For metastatic kidney cancer, targeted drug therapies are one of the main treatment options.⁴

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 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.

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)
- Second-line setting with a cohort evaluating casdatifan plus cabozantinib, a TKI, in immunotherapy-experienced patients (ongoing)
- Late-line setting with 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 metastatic 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 Ivonescimab

Ivonescimab, known as SMT112 in Summit's license territories, North America, South America, Europe, the Middle East, Africa, and Japan, and as AK112 outside of Summit's license territories, is a novel, potential first-in-class investigational bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking VEGF into a single molecule. By design, ivonescimab displays unique cooperative binding to each of its intended targets with multifold higher affinity to PD-1 when in the presence of VEGF.

This design is intended to differentiate ivonescimab as there is potentially higher expression (presence) of both PD-1 and VEGF in tumor tissue and the tumor microenvironment (TME) as compared to normal tissue in the body. Summit believes ivonescimab's specifically engineered tetravalent structure (four binding sites) enables higher avidity (accumulated strength of multiple binding interactions) in the TME (Zhong, et al, iScience, 2025). This tetravalent structure, the intentional novel design of the molecule, and bringing these two targets into a single bispecific antibody with cooperative binding qualities have the potential to direct ivonescimab to the tumor tissue versus healthy tissue. The intent of this design, together with a half-life of 6 to 7 days after the first dose (Zhong, et al, iScience, 2025) increasing to approximately 10 days at steady state dosing, is to improve upon previously established efficacy thresholds, side effects, and safety profiles associated with prior approved drugs to these

targets.

Ivonescimab was engineered by Akeso Inc. (HKEX Code: 9926.HK) and is currently utilized in multiple Phase III clinical trials. Over 4,000 patients have been treated with ivonescimab in clinical studies globally, and over 70,000 patients when considering those treated in a commercial setting in China, as noted by Akeso.

There are currently 15 Phase III clinical studies that are either announced, ongoing, or have been completed studying ivonescimab, four of which are Summit-sponsored global studies, one of which is a multiregional study sponsored by a cooperative group, and 10 of which are being or have been conducted in China by Akeso. Summit began its clinical development of ivonescimab in non-small cell lung cancer (NSCLC), commencing enrollment in 2023 in two multiregional Phase III clinical trials, HARMONi and HARMONi-3. In 2025, Summit began enrolling patients in HARMONi-7. Summit expanded its Phase III clinical development program into colorectal cancer (CRC) in the fourth quarter of 2025 by initiating enrollment in HARMONi-GI3.

HARMONi is a Phase III clinical trial evaluating ivonescimab combined with chemotherapy compared to placebo plus chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a third-generation EGFR TKI (e.g., osimertinib). Detailed results of the study were provided in September 2025, and a Biologics License Application (BLA) was submitted to the United States Food and Drug Administration (FDA) for marketing authorization, which the FDA accepted for filing in January 2026; the goal Prescription Drug User Fee Act (PDUFA) date is November 14, 2026.

HARMONi-3 is a Phase III clinical trial evaluating ivonescimab combined with chemotherapy compared to pembrolizumab combined with chemotherapy in patients with first-line metastatic, squamous or non-squamous NSCLC, irrespective of PD-L1 expression. The clinical trial is evaluating the two histologies as individual, separately powered cohorts with independent statistical powering.

HARMONi-7 is a Phase III clinical trial evaluating ivonescimab monotherapy compared to pembrolizumab monotherapy in patients with first-line metastatic NSCLC whose tumors have high PD-L1 expression.

HARMONi-GI3 is a Phase III clinical trial evaluating ivonescimab in combination with chemotherapy compared with bevacizumab plus chemotherapy in patients with first-line unresectable metastatic CRC.

ILLUMINE is a Phase III study being conducted by GORTEC, a cooperative group dedicated to Head and Neck Oncology, in recurrent / metastatic head and neck squamous cell carcinoma (r/m HNSCC). ILLUMINE is a three-arm Phase III clinical trial designed to evaluate ivonescimab monotherapy, as well as ivonescimab in combination with ligufalimab, Akeso's proprietary anti-CD47 monoclonal antibody, compared to monotherapy pembrolizumab in patients with PD-L1 positive r/m HNSCC.

In addition, Akeso has recently had positive read-outs in three single-region (China), randomized Phase III clinical trials, HARMONi-A, HARMONi-2, and HARMONi-6, for ivonescimab in NSCLC, including a statistically significant overall survival benefit in both the HARMONi-A and HARMONi-6 studies, and a manageable safety profile in each study.

HARMONi-A was a Phase III clinical trial which evaluated ivonescimab combined with chemotherapy compared to placebo plus chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with an EGFR TKI.

HARMONi-2 is a Phase III clinical trial evaluating monotherapy ivonescimab against monotherapy pembrolizumab in patients with locally advanced or metastatic NSCLC whose tumors have positive PD-L1 expression.

HARMONi-6 is a Phase III clinical trial evaluating ivonescimab in combination with platinum-based chemotherapy compared with tislelizumab, an anti-PD-1 antibody, in combination with platinum-based chemotherapy in patients with locally advanced or metastatic squamous NSCLC, irrespective of PD-L1 expression.

Akeso is actively conducting multiple Phase III clinical studies in settings outside of NSCLC, including biliary-tract cancer, triple-negative breast cancer, head and neck squamous cell carcinoma, small cell lung cancer, colorectal cancer, and pancreatic cancer.

Ivonescimab is an investigational therapy that is not approved by any regulatory authority in Summit's license territories, including the United States and Europe. Ivonescimab was initially approved for marketing authorization in China in May 2024.

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 Summit Therapeutics Inc.

Summit Therapeutics Inc. is a biopharmaceutical oncology company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs.

Summit was founded in 2003 and the company's shares are listed on the Nasdaq Global Market (symbol "SMMT"). Summit is headquartered in Miami, Florida, with additional offices in Palo Alto, California, Princeton, New Jersey, Dublin, Ireland, and Oxford, UK.

For more information, please visit <https://www.smmmtx.com> and follow Summit on X @SMMT_TX.

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, Arcus's development strategy for casdatifan, the timing and achievement of milestones, the potential advantages of the combination to provide improved outcomes for patients, including survival. 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; the unexpected emergence of adverse events or other undesirable side effects with casdatifan or casdatifan-based combinations; 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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Summit Forward-Looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates, entry into and actions related to the Company's partnership with Akeso Inc. and other collaborations, the intended use of the net proceeds from the private placements, the Company's anticipated spending and cash runway, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, the expected timing of BLA submissions or FDA decisions, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, the Company's estimates regarding stock-based compensation, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the Company's ability to sell shares of our common stock under the ATM Program, the conditions affecting the capital markets, general economic, industry, or political conditions, including the effects of geopolitical developments, domestic and foreign trade policies, and monetary policies, the results of our evaluation of the underlying data in connection with the development and commercialization activities for ivonescimab, the outcome of discussions with regulatory authorities, including the Food and Drug Administration, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials, the results of such trials, and their success, global public health crises, that may affect timing and status of our clinical trials and operations, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, whether business development opportunities to expand the Company's pipeline of drug candidates, including without limitation, through potential acquisitions of, and/or collaborations with, other entities occur, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Summit defines a "positive study" as a clinical study with one or more prespecified primary endpoints in which one of those endpoints achieves a statistically significant benefit according to the protocol or statistical analysis plan. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ivonescimab. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release and

should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

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