Arsenal Biosciences Announces First Patient Dosed in Phase 1/2 Clinical Trial of AB-2100 in Development as a Treatment for Clear-cell Renal Cell Carcinoma

South San Francisco, Calif. – April 30, 2024 – Arsenal Biosciences, Inc. (ArsenalBio), a clinical stage programmable cell therapy company focused on engineering advanced CAR T-cell therapies for solid tumors, today announced that the first patient has been dosed with AB-2100 in a multi-center, open-label Phase 1/2 clinical trial for patients with clear-cell renal cell carcinoma (ccRCC). AB-2100 utilizes ArsenalBio's CITE (CRISPR Integration of Transgenes by Electroporation) technology to engineer T cells to selectively target the tumor and overcome the suppressive tumor microenvironment. These engineering features will potentially enable the patient's immune system to destroy ccRCC cells without harming normal tissues.

"Kidney cancer is an immunologically responsive malignancy with several FDA approved immunotherapies on the market. But despite much progress in the field, there remains a tremendous unmet need in this indication, which we believe our Integrated Circuit T (ICT) cell technology is ideally suited to address," said Susie Jun, M.D., Ph.D., ArsenalBio's Chief Medical Officer. "As with our AB-1015 program in ovarian cancer, we hope this study succeeds in identifying a safe and therapeutic dose to enable further study of this potential therapy in larger patient cohorts."

The Phase 1/2 trial (NCT06245915) is a dose escalation study that will evaluate the safety and efficacy of AB-2100 in patients with ccRCC that either came back or did not improve after treatment with a checkpoint inhibitor and a VEGF inhibitor. The goal of the study is to determine the maximum tolerated dose of AB-2100, which is administered intravenously via a single infusion following completion of conditioning chemotherapy. The study is expected to enroll up to 60 patients in Phase 1 and 130 patients total across multiple clinical sites in the United States.

AB-2100 is an ICT cell therapy engineered with the intent to treat ccRCC. The foundational manufacturing technique is precise and specific CRISPR-mediated insertion of a large synthetic double-stranded DNA cassette into a novel safe harbor site in Chromosome 11. The cassette encodes several features: a synthetic logic gate designed to optimize how the ICT cells target tumors and avoid normal tissues by requiring the presence of two distinct proteins in ccRCC (prostate-specific membrane antigen (PSMA) on tumor endothelium and carbonic anhydrase 9 (CA9) on the adjacent tumor cell); shRNAs to armor the T cell against immunosuppressive signals in the TME; and a novel synthetic pathway activator (SPA) designed to increase the potency and functional persistence of the engineered T cells.

"Our logic gate approach was designed to selectively target tumors and spare normal tissues by requiring the presence of two antigens in close proximity," said Dr. Jun. "Based upon our

preclinical data we believe this synthetic biology-based logic gate approach will enable targeting of antigens like CA9 where conventional CAR T-cell strategies have been limited by on-target toxicity in healthy tissues."

AB-2100 is ArsenalBio's second internally discovered T cell therapeutic candidate to enter clinical development. A multi-center, open-label phase 1 dose escalation trial (NCT05617755) of AB-1015, under investigation for the treatment of ovarian cancer, is currently enrolling.

About Arsenal Biosciences Inc.
Arsenal Biosciences, Inc. (ArsenalBio), headquartered in South San Francisco, Calif., is a clinical stage programmable cell therapy company focusing on discovering and developing a pipeline of next-generation autologous T cell therapies to defeat cancer. Our full-stack R&D engine is designed to generate multifunctional T cell medicines, enabled by precise and specific CRISPR-mediated insertion of large synthetic DNA cassettes. ArsenalBio is aiming to build the industry's largest DNA library of potential therapeutic enhancing integrated circuits, incorporating logic gating for improved tumor targeting and synthetic features enabling multiple pharmaceutical functions. In pioneering a computationally driven approach alongside nonviral clinical manufacturing, we aspire to deliver enhanced efficacy, increased patient safety, reduced stakeholder costs, and expanded market access. To learn more, visit www.arsenalbio.com and follow us on X (Twitter) @ArsenalBio, LinkedIn, and Facebook.

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