SuviCa, CU Boulder, and CU Anschutz Announce Positive FDA Pre-IND Feedback for SVC112 Program in Advanced Solid Tumors

BOULDER, CO, UNITED STATES, July 7, 2026 /EINPresswire.com/ -- SuviCa, Inc., along with the University of Colorado Boulder and the University of Colorado Anschutz, today announced the successful completion of a Type B Pre-Investigational New Drug (pre-IND) interaction with the U.S. Food and Drug Administration (FDA) for SVC112, the company's first-in-class protein synthesis inhibitor being developed for the treatment of advanced and metastatic solid tumors.

The FDA provided written responses to SuviCa's pre-IND submission and indicated that the nonclinical studies completed, planned, and ongoing for SVC112 "appear sufficient to support the proposed first-in-human study." The Agency also stated that SuviCa's proposed approach to determining the first-in-human starting dose "appears reasonable."

"We are very encouraged by the FDA's feedback and believe this represents an important milestone in the development of SVC112," said Antonio Jimeno, MD, PhD, CU Anschutz Professor, Medicine-Medical Oncology, and Board member of SuviCa. "The Agency's responses support our development strategy and provide a clear regulatory path toward IND submission and initiation of our first-in-human clinical study, added Dr. Jimeno. "The innovative support network at the University of Colorado's Boulder and Anschutz campuses has made all this possible," said Tin Tin Su, PhD, CU Boulder Professor, lead inventor of SVC112, and co-founder of SuviCa.

SVC112 is a synthetic analog of the natural product Bouvardin and is designed to inhibit protein synthesis through targeting eukaryotic elongation factor 2 (eEF2). The compound has demonstrated anti-tumor activity in preclinical studies and is being developed to address tumors characterized by aggressive growth and treatment resistance.

SuviCa's planned Phase 1 clinical trial is an open-label, dose-escalation and dose-expansion study evaluating intravenous SVC112 in patients with advanced or metastatic solid tumors who have exhausted standard treatment options. The study is designed to establish the recommended Phase 2 dose, characterize safety and pharmacokinetics, and evaluate preliminary anti-tumor activity and biomarker response.

The FDA also indicated that it had no objections to the proposed dosing frequency, provided the regimen is supported by ongoing GLP toxicology studies. In addition, the Agency recommended refinements to dose-limiting toxicity criteria and encouraged future discussions once preliminary

clinical response data become available.

SuviCa plans to submit its IND application following completion of ongoing GLP toxicology studies and finalization of CMC activities.

About SVC112

SVC112 is a novel small molecule inhibitor of protein synthesis designed to selectively disrupt cancer stemness pathways and MYC-driven tumor biology. By inhibiting elongation during protein translation, SVC112 has the potential to target tumors resistant to conventional therapies.

About SuviCa, Inc.

SuviCa, Inc. is a biotechnology company focused on developing novel therapeutics targeting cancer stemness and translational control mechanisms in oncology. The company's lead program, SVC112, is being developed for advanced solid tumors with high unmet medical need. Based on the compelling efficacy and safety profiles of its lead drug candidate, SVC112, SuviCa received support from the National Cancer Institute (NCI) Experimental Therapeutics (NExT) Program to develop SVC112 for salivary gland cancer (SGC). NCI is part of the National Institutes of Health. SVC112 is being developed in collaboration between Dr. Tin Tin Su (CU Boulder, MCD Biology) and Dr. Antonio Jimeno (CU Anschutz School of Medicine-Medical Oncology), and further development of SVC112 is being supported by the Anschutz Acceleration Initiative.

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About the University of Colorado Anschutz
The University of Colorado Anschutz is a world-class academic medical campus leading transformative advances in science, medicine, education and patient care. The campus includes the University of Colorado's health professional schools, more than 60 centers and institutes, and two nationally ranked independent hospitals - UCHealth University of Colorado Hospital and Children's Hospital Colorado - which conduct nearly 3 million adult and pediatric patient visits each year. Innovative, interconnected and highly collaborative, CU Anschutz delivers life-changing treatments, exceptional patient care and top-tier professional training. The campus conducts world-renowned research supported by $890 million in funding, including $762 million in sponsored awards and $128 million in philanthropic gifts for research.

About the University of Colorado Boulder
CU Boulder is Colorado's leading public research university, transforming lives since 1876. As the state's flagship university and one of only 38 U.S. public research institutions in the Association of American Universities (AAU), CU Boulder has proudly served Coloradans since the state's

founding. Home to five Nobel Laureates since 1989 and the only university to send space instruments to every planet in the solar system, CU Boulder provides a strong return on investment by aligning efforts to achieve research and creative excellence, global sustainability impact and the success of all students, faculty and staff. Learn more about commercialization activities by Venture Partners at CU Boulder at colorado.edu/venturepartners.

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