Clover and Ascentage Pharma Announce Clinical Collaboration to Evaluate Recombinant Human TRAIL-Trimer Fusion Protein, SCB-313, in Combination with IAP Antagonist, APG-1387 for the Treatment of Peritoneal Carcinomatosis

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CHENGDU, SUZHOU, China, and ROCKVILLE, Md., Dec. 09, 2021 (GLOBE NEWSWIRE) -- Clover Biopharmaceuticals, Ltd. (Clover; Stock Code: 2197.HK), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutic candidates and Ascentage Pharma (6855.HK), a globally focused biopharmaceutical company engaged in developing novel therapies for cancers, chronic hepatitis B (CHB), and age-related diseases, today announced that they have entered into a clinical collaboration to evaluate Clover's SCB-313, a recombinant human TRAIL-Trimer fusion protein and Ascentage Pharma's APG-1387, a second mitochondria-derived activator of caspase (SMAC)-mimetic/inhibitor of apoptosis proteins (IAP) antagonist, in a Phase 1b/2 clinical trial for advanced peritoneal carcinomatosis.

Clover and Ascentage Pharma will jointly conduct this open-label, multicenter, Phase 1b/2 study to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics (PK/PD), and efficacy of SCB-313 in combination with APG-1387 for the treatment of patients with primary or secondary peritoneal carcinomatosis from different primary tumor origins. The trial will be conducted at multiple sites in China and Australia.

Clover's SCB-313 is a trimeric fusion protein in clinical development for the treatment of intracavitary malignancies. Based on positive Phase 1 interim analyses, Clover plans to advance SCB-313 into a Phase 2 clinical trial for malignant ascities in the first half of 2022. SCB-313 is also in Phase 1 clinical trials for malignant pleural effusions and peritoneal carcinomatosis. Clover also plans to initiate new Phase 1 trials for SCB-313 in new indications, such as bladder cancer, in 2022.

Discovered and developed by Ascentage Pharma, APG-1387 is a potent and highly specific next-generation IAP antagonist and the first IAP antagonist entering clinical development in China. To advance the clinical development of APG-1387 globally, Ascentage Pharma has completed a Phase 1 dose-escalation for the treatment of solid tumors in China and Australia and is currently conducting multiple clinical studies of APG-1387 combinations for the treatment of solid tumors in China and the US. Meanwhile, APG-1387 is also being evaluated in a Phase 2 study in patients with chronic hepatitis B (HBV) infections in China.

"Clover is excited to enter into this partnership with Ascentage Pharma to explore innovative treatment options and alternatives to surgery for patients suffering from peritoneal carcinomatosis," said **Joshua Liang, Chief Executive Officer of Clover Biopharmaceuticals.** "Combination treatment is a cornerstone of cancer therapy. By targeting different nodes within the apoptosis pathway, we believe the combination of SCB-313 and APG-1387 could provide a synergistic benefit to patients."

"Safe and effective combination therapies represent an increasingly important approach in cancer treatment. We hope APG-1387 in combination with Clover's SCB-313 will demonstrate synergistic effect," said **Dr. Dajun Yang, Chairman & CEO of Ascentage Pharma.** "We look forward to working closely with Clover to advance this clinical collaboration which hopefully will offer a new treatment option to patients with peritoneal carcinomatosis."

About SCB-313

SCB-313 is an innovative, recombinant human TNF-related apoptosis-inducing ligand (TRAIL)-Trimer fusion protein engineered using the Trimer-Tag™ technology platform to target the extrinsic apoptosis pathway. Binding of SCB-313 to the death receptors (DR4 and DR5) leads to physiologic trimerization and potent activation of the extrinsic apoptosis pathway.

About Clover Biopharmaceuticals

Clover Biopharmaceuticals is a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates. The Trimer-Tag™ technology platform is a product development platform for the creation of novel vaccines and biologic therapies. Clover leveraged the Trimer-Tag™ technology platform to become a COVID-19 vaccine developer and created SCB-2019 (CpG 1018/Alum) to address the COVID-19 pandemic caused by SARS-CoV-2.

For more information, please visit our website: www.cloverbiopharma.com and follow the company on LinkedIn.

About APG-1387

Discovered and developed by Ascentage Pharma, APG-1387 is a potent and highly selective next-generation inhibitor of apoptosis proteins (IAP) antagonist that can degrade IAPs by mimicking endogenous second mitochondria-derived activator of caspase (SMAC) molecule to induce programmed cell death or apoptosis. To advance the clinical development of APG-1387 globally, Ascentage Pharma has already completed a Phase I dose-escalation study in patients with solid tumors in China and Australia, and is currently conducting a Phase Ib/II clinical study of the APG-1387 plus pembrolizumab combination in patients with solid tumors in the US, and a Phase Ib/II study of APG-1387 plus nab-paclitaxel plus gemcitabine in patients with advanced pancreatic cancer in China. Moreover, APG-1387 is also being evaluated in a Phase II study in patients with chronic hepatitis B (HBV) infections in China.

About Ascentage Pharma

Ascentage Pharma (6855.HK) is a globally focused biopharmaceutical company engaged in developing novel therapies for cancers, chronic hepatitis B, and age-related diseases. On October 28, 2019, Ascentage Pharma was listed on the Main Board of the Stock Exchange of Hong Kong Limited with the stock code 6855.HK.

Ascentage Pharma focuses on developing therapeutics that inhibit protein-protein interactions to restore apoptosis, or programmed cell death. The company has built a pipeline of eight clinical drug candidates, including novel, highly potent Bcl-2, and dual Bcl-2/Bcl-xL inhibitors, as well as candidates aimed at IAP and MDM2-p53 pathways, and next-generation tyrosine kinase inhibitors (TKIs). Ascentage Pharma is also the only company in the world with active clinical programs targeting all three known classes of key apoptosis regulators. The company is conducting more than 40 Phase I/II clinical trials in the US, Australia, Europe, and China. Olverembatinib, the company's core drug candidate developed for the treatment of drug-resistant chronic myeloid leukemia (CML), was granted Priority Review status and a Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of China National Medical Products Administration (NMPA), and is already approved for the indication. In addition, the olverembatinib was also granted an Orphan Drug Designation (ODD) and a Fast Track Designation (FTD) by the US FDA, and an Orphan Designation by the EU. To date, Ascentage Pharma has obtained a total of 12 ODDs from the US FDA and 1 ODD from the EU for four of the company's investigational drug candidates. Ascentage Pharma has been designated for multiple Major National R&D Projects, including five National Major New Drug Discovery and Manufacturing projects, one New Drug Incubator status, four Innovative Drug Programs, and one Major Project for the Prevention and Treatment of Infectious Diseases.

Leveraging its robust R&D capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights and entered into global partnerships with numerous renowned biotechnology and pharmaceutical companies and research institutes such as UNITY Biotechnology, MD Anderson Cancer Center, Mayo Clinic, Dana-Farber Cancer Institute, MSD, AstraZeneca, and Pfizer. The company has built a talented team with global experience in the discovery and development of innovative drugs and is setting up its world-class commercial manufacturing and Sales & Marketing teams. One pivotal aim of Ascentage Pharma is to continuously strengthen its R&D capabilities and accelerate its clinical development programs, in order to fulfil its mission of addressing unmet clinical needs in China and around the world for the benefit of more patients.

Clover Forward-looking Statements

This press release contains certain forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this [document], the words “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “going forward,” “intend,” “may,” “might,” “ought to,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. We give no assurance that these expectations and assumptions will prove to have been correct. Because forward-looking statements relate to the future, they are participant to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. We caution you therefore against placing undue reliance on any of these forward-looking statements. Any forward-looking statement made by us in this document speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. Participant to the requirements of applicable laws, rules and regulations, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

Ascentage Pharma’s Forward-Looking Statements
The forward-looking statements made in this article relate only to the events or information as of the date on which the statements are made in this article. Except as required by law, Ascentage Pharma undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this article completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this article, statements of, or references to, our intentions or those of any of our Directors or our Company are made as of the date of this article. Any of these intentions may alter in light of future development.

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