



Clover Doses First Patient with SCB-219M in Phase 1 Trial for Chemotherapy-Induced Thrombocytopenia

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-- Phase 1 study to evaluate the safety, tolerability, pharmacokinetics and efficacy of SCB-219M in cancer patients with chemotherapy-induced thrombocytopenia, a serious treatment-associated platelet count disorder --

-- Interim safety and recommended Phase 2 dose anticipated in first half of 2023 --

SHNAGHAI, China, June 14, 2022 (GLOBE NEWSWIRE) -- [Clover Biopharmaceuticals, Ltd. \(Clover: HKEX: 02197\)](#), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutic candidates today announced that the first patient has been dosed with SCB-219M, an innovative thrombopoietin receptor agonist (TPO-RA) mimetic Fc-fusion protein, in a Phase 1 clinical trial to evaluate the safety, tolerability, immunogenicity, pharmacokinetics, and efficacy of SCB-219M in cancer patients with chemotherapy-induced thrombocytopenia (CIT). Clover received IND approval for SCB-219M as a Class I new drug from the CDE in December 2021.

"CIT is a serious, chemotherapy-associated complication observed in a wide range of cancer patients. Incidence of CIT can occur in greater than 50%¹ of patients undergoing standard chemotherapy regimens, and can have detrimental impacts on treatment outcome, resulting in chemotherapy dose delay or dose reduction, and potentially fatal bleeding events," **said Dr. Peng Liang, Founder, Chief Scientific Officer of Clover and inventor of SCB-219M.** "CIT remains a pressing unmet medical need for patients undergoing cancer treatment, and we look forward to evaluating SCB-219M in weekly dosing regimens, in contrast to current standard of cares which mostly require daily injection or medication."

The Phase I trial is a multi-center, open-label, dose escalation and dose expansion study, that will explore the safety, tolerability, immunogenicity, pharmacokinetics, and efficacy of SCB-219M administered subcutaneously in cancer patients with CIT. Interim safety and recommendations for Phase II dosing is anticipated in the first half of 2023.

About SCB-219M

SCB-219M is an innovative human thrombopoietin receptor agonist (TPO-RA) produced from CHO cells based on Clover's Fc-fusion technology platform. In pre-clinical studies, SCB-219M has demonstrated an extended serum half-life and favorable pharmacokinetics /pharmacodynamics (PK/PD) profile that supports weekly dosing possibility of the drug. In comparison, current standard of cares for CIT largely require either daily injection or drug administration.

About Chemotherapy-induced Thrombocytopenia (CIT)

Chemotherapy-induced thrombocytopenia (CIT) is a platelet count disorder typically observed in cancer patients undergoing chemotherapy. CIT negatively affects overall chemotherapy treatment outcomes due to therapeutic interruption and serious, potentially fatal bleeding events. Primary treatment options for CIT in the United States and Europe include platelet transfusion, providing short-term stability of platelet levels, and in China include recombinant human interleukin 11 (rh IL-11) and recombinant humanized thrombopoietin (rh-TPO) which requires daily injection for no more than 14 days due to potential significant adverse reactions such as anti-drug antibody generation (ADAs).

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 Clover's website: www.cloverbiopharma.com and follow the company on [LinkedIn](#).

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, 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.

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¹ Ying Wu, Suresh Aravind, Gayatri Ranganathan, et al. Anemia and thrombocytopenia in patients undergoing chemotherapy for solid tumors: A descriptive study of a large outpatient oncology practice database, 2000– 2007[J]. Clinical Therapeutics, Volume 31, Part 2,2009, Pages 2416-2432