Clover Announces Positive Phase Ⅰ Results for SCB-219M for Treatment of Chemotherapy-Induced Thrombocytopenia (CIT)

--All CIT patients maintained platelet counts >75 x 10^9/L at 1-week following chemotherapy plus a single dose of SCB-219M, with durable responses through at least 3-weeks--

--Durable efficacy and PK profile expected to support convenient dosing interval of ≥2-weeks, compared to daily or weekly dosing for current treatment options in China[1] and globally[2]--

--Phase Ⅰb trial in CIT and CTIT (cancer treatment-induced thrombocytopenia) patients evaluating repeated dosing of SCB-219M is planned to initiate in 2024--

CHENGDU, Dec. 29, 2023 /PRNewswire/ -- Clover Biopharmaceuticals, Ltd. (Clover; HKEX: 02197), a global commercial-stage biotechnology company, today announced positive preliminary safety, efficacy and pharmacokinetics data in a Phase Ⅰ clinical trial evaluating SCB-219M, an innovative thrombopoietin receptor agonist (TPO-RA) mimetic bispecific Fc-fusion protein produced from CHO cells, for the treatment of cancer patients with chemotherapy-induced thrombocytopenia (CIT).

All cancer patients enrolled to-date (n=9) receiving chemotherapy plus a single subcutaneous dose of SCB-219M observed platelet counts maintained or recovered at >75 x 10^9/L (threshold level for CIT) after one week, with responses durable through at least three weeks (i.e. through the chemotherapy cycle). In comparison, following administration of the same chemotherapy (but without SCB-219M) in the same cancer patients prior to enrolling into the trial, all evaluable patients had observed platelet counts drop to <75 x 10^9/L between one and three weeks. The durable preliminary efficacy and pharmacokinetic profile observed for SCB-219M are potentially supportive of dosing intervals ≥2-weeks. If further confirmed, this profile could enable convenient dosing of SCB-219M synchronized with any given patient's chemotherapy regimen, typically 2-3 weeks per cycle. A favorable safety and tolerability profile for SCB-219M has also been observed to-date, with no serious adverse events (SAEs) and no dose-limiting toxicity (DLT) identified.

Dr. Yongsheng Wang, Associate Director of West China Hospital Cancer Center at Sichuan University and Principal Investigator for the SCB-219M Phase Ⅰ Trial commented: "We are encouraged by the Phase Ⅰ results to-date for SCB-219M, and we look forward to the continued evaluation of SCB-219M, as we believe the management of CIT remains a pressing unmet medical need for patients undergoing cancer treatment."

"We are pleased to announce positive Phase Ⅰ results for SCB-219M demonstrating rapid and durable efficacy along with a favorable safety profile,"said **Dr. Peng Liang, Chairman, Chief Scientific Officer of Clover and inventor of SCB-219M.** "The preliminary results suggest that SCB-219M has a potentially differentiated profile compared to the current standard of care treatments for CIT and CTIT. In contrast to current biologic treatment options for CIT in China requiring daily injections[1] and globally requiring weekly injections[2], the durable efficacy and pharmacokinetics of SCB-219M observed to-date could enable convenient dosing synchronized with any given patient's chemotherapy regimen."

The Phase Ⅰ trial is a multi-center, open-label, dose escalation and dose expansion study, that is exploring the safety, tolerability, immunogenicity, pharmacokinetics, and efficacy of SCB-219M administered

subcutaneously in cancer patients with CIT. In addition to West China Hospital Cancer Center at Sichuan University, other participating sites in this clinical trial include Sichuan Provincial People's Hospital and Chengdu No. 6 People's Hospital. A Phase Ⅰb trial evaluating repeated dosing of SCB-219M in CIT and CTIT patients is planned to initiate in 2024.

CIT is a serious, chemotherapy-associated complication observed in a wide range of cancer patients. Incidence of CIT can occur in greater than 50%[3] of patients undergoing standard chemotherapy regiments, and can have detrimental impacts on treatment outcome, resulting in chemotherapy dose delay or dose reduction, and potentially fatal bleeding events.

1. TPIAO (3SBio; https://ypk.39.net/666055/manual).

2. Nplate; romiplostim (https://doi.org/10.3324/haematol.2020.251900; https://doi.org/10.1200/JCO.18.01931).

3. 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

About Clover

Clover Biopharmaceuticals is a global commercial-stage biotechnology company committed to unleashing the power of innovative vaccines and biologics to save lives and improve health around the world. With integrated research and development, manufacturing and commercial capabilities as well as strong partnerships with organizations globally, Clover has a diverse pipeline of candidates that have the potential to meaningfully reduce the burden of vaccine-preventable diseases—and to make more diseases preventable.

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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