Chemomab Reports Top-Line Results from CM-101 Phase 2a Liver Fibrosis Biomarker Trial in NASH Patients

—CM-101 Met Primary Endpoint of Safety and Tolerability and Showed Positive Activity Across Multiple Liver Fibrosis Biomarkers and Physiologic Assessments—

TEL AVIV, Israel, Jan. 3, 2023 /<u>PRNewswire</u>/ -- Chemomab Therapeutics, Ltd. (Nasdaq: CMMB) (Chemomab), a clinicalstage biotechnology company focused on the discovery and development of innovative therapeutics for fibrotic and inflammatory diseases with high unmet need, today reported top-line results from its Phase 2a trial assessing CM-101, its first-in-class CCL24-neutralizing monoclonal antibody, in non-alcoholic steatohepatitis (NASH) patients. The trial met its primary endpoint of safety and tolerability, and CM-101 achieved reductions in secondary endpoints that include a range of liver fibrosis biomarkers and physiologic assessments measured at baseline and at week 20.

The randomized, placebo-controlled trial enrolled 23 NASH patients with stage F1c, F2 and F3 disease who were randomized to receive either CM-101 or placebo. Patients received eight doses of 5 mg/kg of CM-101 or placebo, administered by subcutaneous (SC) injection once every two weeks, for a treatment period of 16 weeks. This trial was primarily designed to assess the subcutaneous formulation of CM-101 and to evaluate the drug's impact on liver fibrosis biomarkers relevant to both NASH and the rare fibro-inflammatory conditions that represent the focus for the company, such as primary sclerosing cholangitis (PSC) and systemic sclerosis (SSc).

Dale Pfost, PhD, Chief Executive Officer of Chemomab, said, "It is noteworthy that this trial confirmed the safety and tolerability of CM-101 and the pharmacokinetics of our subcutaneous formulation, while providing biomarker data further demonstrating the anti-inflammatory and anti-fibrotic activity of CM-101. We are especially pleased with these encouraging findings given the small size of the study, the short duration of treatment and the relatively low dose of CM-101 that was administered."

Dr. Pfost continued, "This is the third clinical trial in patients demonstrating the activity of CM-101 as measured by fibroinflammatory biomarkers and physiological assessments. It confirms similar data we reported in our <u>Phase 1b study</u> in patients with non-alcoholic fatty liver disease (NAFLD) and in our recently reported investigator study of <u>acute lung</u> injury in <u>COVID patients</u>. Collectively, these data encompassing diverse organs and conditions reinforce our optimism about our ongoing Phase 2 trial in primary sclerosing cholangitis and our Phase 2 trial in systemic sclerosis that is scheduled to begin early this year."

Key findings of the CM-101 Phase 2a trial included the following.

- **CM-101 continues to appear safe and was well tolerated when administered subcutaneously**. Most reported adverse events observed were mild, with one unrelated serious adverse event reported. No significant injection site reactions were observed and no anti-drug antibodies were detected.
- CM-101 administered subcutaneously demonstrated favorable pharmacokinetics and target engagement profiles as expected; they were similar to what the company has previously reported.
- CM-101-treated patients showed greater improvements than the placebo group in a number of liver fibrosis-related biomarkers, including ProC-3, ProC-4, ProC-18, TIMP-1 and ELF.
- A majority of CM-101-treated patients showed improvements in more than one liver fibrosis-related biomarker—almost 60% of CM-101-treated patients responded in at least three biomarkers at week 20, compared to no patients in the placebo group.
- CM-101-treated patients with higher CCL24 levels at baseline showed greater reductions in fibrosisrelated biomarkers than patients with lower CCL24 levels. Patients with higher CCL24 at baseline were also more likely to be responders in multiple fibrosis-related biomarkers than patients with lower CCL24 levels, adding to the growing body of evidence validating the role of CCL24 in the pathophysiology of fibrotic liver disease.
- A higher proportion of patients in the CM-101-treated group showed improvement in a physiologic measure of liver stiffness as compared to placebo (reduction of at least one grade of fibrosis score as assessed by the non-invasive elastography method known as FibroScan[®]).
- After completion of the study, the unblinded data showed that patients in the CM-101-treated group had higher baseline levels of fibrosis compared to placebo-treated patients. The impact of this difference on the results, if any, is unknown.

Massimo Pinzani, MD, PhD, Professor of Medicine, Director of the University College London (UCL) Institute for Liver and Digestive Health and the Sheila Sherlock Chair of Hepatology at UCL, commented, "These encouraging Phase 2a results for CM-101 are a good example of what one is seeking in a successful biomarker study-sets of multiple biomarkers moving together in a positive direction. Based on these early findings, CM-101 may have the potential to interrupt the inflammatory and fibrotic vicious cycle characterizing conditions such as PSC, systemic sclerosis and other fibro-inflammatory diseases, providing the potential for much-needed disease-modifying therapy."

Rifaat Safadi, MD, Professor in Medicine, Gastroenterology and Hepatology, Faculty of Medicine, Hadassah University Hospital, Jerusalem; a Visiting Scholar at the Division of Liver Diseases, Mount Sinai School of Medicine in New York City, and Principal Investigator of the Phase 2a study noted, "The results from this early trial confirm previous clinical and preclinical research suggesting that neutralizing the pro-fibrotic and pro-inflammatory effects of CCL24 may have a therapeutic benefit for patients battling intractable fibro-inflammatory diseases such as PSC and systemic sclerosis, and support the conduct of additional clinical trials to address this unmet medical need. I want to thank the patients who participated in this trial and the team members at the clinical sites who helped make these encouraging results possible."

For more information on Chemomab's Phase 2 SPRING trial In patients with primary sclerosing cholangitis, visit <u>www.chemomab.com/trials/psc/</u>, or <u>click here</u> for information for potential participants.

About Chemomab Therapeutics

Chemomab is a clinical stage biotechnology company focusing on the discovery and development of innovative therapeutics for fibrotic and inflammatory diseases with high unmet need. Based on the unique and pivotal role of the soluble protein CCL24 in promoting fibrosis and inflammation, Chemomab developed CM-101, a monoclonal antibody designed to bind and block CCL24 activity. CM-101 has demonstrated the potential to treat multiple severe and life-threatening fibrotic and inflammatory diseases. A Phase 2 liver fibrosis biomarker study in NASH patients was recently completed and a Phase 2 trial in primary sclerosing cholangitis patients is ongoing. Chemomab expects to begin enrolling patients in a Phase 2 trial in systemic sclerosis early in 2023. For more information on Chemomab, visit chemomab.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. These forward-looking statements include, among other things, statements regarding the clinical development pathway for CM-101 and the results of the Phase 2a Liver Fibrosis Biomarker trial in NASH patients on future development plans; the future operations of Chemomab and its ability to successfully initiate and complete clinical trials and achieve regulatory milestones; the nature, strategy and focus of Chemomab; the development and commercial potential and potential benefits of any product candidates of Chemomab; and that the product candidates have the potential to address high unmet needs of patients with serious fibrosis-related diseases and conditions. Any statements contained in this communication that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements are based upon Chemomab's current expectations. Forward-looking statements involve risks and uncertainties. Because such statements deal with future events and are based on Chemomab's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Chemomab could differ materially from those described in or implied by the statements in this presentation, including: risks related to Chemomab's ability to effectively implement the revised clinical strategy and its ability to achieve the anticipated results; risks related to the projections and associated benefits in pursuing the contemplated changes to the clinical strategy; risks associated with the ongoing transitions of certain of our executive officers, including Chemomab's new Chief Executive Officer; the uncertain and time-consuming regulatory approval process; risks related to Chemomab's ability to correctly manage its operating expenses and its expenses; Chemomab's plans to develop and commercialize its product candidates, focusing on CM-101; the timing of initiation of Chemomab's planned clinical trials: the timing of the availability of data from Chemomab's clinical trials including any potential delays associated with Chemomab's contemplated revised clinical strategy; the timing of any planned investigational new drug application or new drug application; Chemomab's plans to research, develop and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of Chemomab's product candidates; Chemomab's commercialization, marketing and manufacturing capabilities and strategy; Chemomab's ability to protect its intellectual property position; and the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all. Additional risks and uncertainties relating to Chemomab's and its business can be found under the caption "Risk Factors" and elsewhere in Chemomab's filings and reports with the SEC. Chemomab expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Chemomab's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based, except to the extent required by applicable law.

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