

Chemomab Announces Completion of Patient Enrollment in CM-101 Phase 2 Primary Sclerosing Cholangitis Trial and Moves Up Expected Topline Readout to Midyear 2024

—Expected Topline Data Readout Accelerated to Midyear 2024 Following Early Completion of Patient Enrollment in Phase 2 Primary Sclerosing Cholangitis (PSC) SPRING Trial—

—CM-101's Unique Dual Anti-Fibrotic and Anti-Inflammatory Activity Has Disease Modifying Potential in PSC, Which Often Results in Liver Transplant or Death and Lacks Any FDA-Approved Treatments—

TEL AVIV, Israel, Jan. 3, 2024 /[PRNewswire](#)/ -- Chemomab Therapeutics Ltd. (Nasdaq: CMMB) (Chemomab), a clinical stage biotechnology company focused on the discovery and development of innovative therapeutics for fibro-inflammatory diseases with high unmet need, today announced early completion of patient enrollment in its Phase 2 clinical trial assessing CM-101 as a treatment for primary sclerosing cholangitis (PSC). The company also announced that it expects to report topline data from the PSC clinical trial by midyear 2024, rather than in the second half of 2024 as previously projected.

"We are delighted we were able to accelerate our expected topline PSC clinical data milestone to midyear 2024 as a result of early completion of patient enrollment in this critical Phase 2 trial," said Adi Mor, PhD, co-founder, Chief Executive Officer and Chief Scientific Officer of Chemomab. "We believe that CM-101 has the potential for disease-modifying activity in PSC, a severe fibro-inflammatory liver disease that has no FDA-approved therapies. We anticipate that positive data from this 68-patient clinical trial would be a major catalyst for Chemomab and allow us to move towards a registrational trial in PSC. Positive data would also set the stage for advancing CM-101 in other fibro-inflammatory diseases such as systemic sclerosis, where we have an open U.S. IND to conduct a Phase 2 clinical trial."

CM-101 is a first-in-class monoclonal antibody that neutralizes the soluble protein CCL24, which in preclinical and clinical studies has been associated with key pathways underlying PSC pathophysiology. CM-101's dual anti-inflammatory and anti-fibrotic activity has demonstrated disease modifying potential in PSC and other fibro-inflammatory disorders. CM-101 has Orphan Drug designation for PSC in the U.S. and the European Union (EU) and was recently awarded Fast Track designation by the U.S. Food & Drug Administration (FDA).

Chemomab Chief Medical Officer Matt Frankel, MD, added, "We appreciate the diligent work of our clinical and medical teams and our collaborators at medical centers around the world who completed enrollment in the PSC trial ahead of projections, as well as the commitment of the many patients and advocacy organizations who contributed to the success of the study to date. We are gratified at the high level of interest the SPRING trial has generated among patients and physicians, highlighting the urgent need for effective PSC therapies."

Chemomab's Phase 2 SPRING trial ([NCT04595825](#)) is a double-blind, placebo-controlled, multiple dose study assessing the safety and tolerability of CM-101 administered to PSC patients with established large duct disease. The trial has completed enrollment of the planned 68 patients in the U.S., EU and Israel. Enrolled patients receive either 10 mg/kg or 20 mg/kg of CM-101 or placebo via an intravenous infusion every three weeks over 15 weeks. The SPRING trial includes an open label extension available to all study participants, who receive infusions of either 10 mg/kg or 20 mg/kg of CM-101 every three weeks for an additional 33 weeks. In addition to safety, the trial is measuring a wide range of secondary outcomes including serum biomarkers and physiological parameters. These include well-validated liver biomarkers such as alkaline phosphatase (ALP), ELF and PRO-C3, as well as FibroScan assessments of liver stiffness.

About CM-101

CM-101 is a monoclonal antibody that neutralizes CCL24, a soluble protein that helps drive the inflammatory and fibrotic pathways central to many fibro-inflammatory diseases. CCL24's role as a therapeutic target has been validated in extensive preclinical studies and Chemomab researchers have demonstrated preclinical proof-of-concept for CM-101 in multiple animal and patient sample studies. CM-101 was safe and well tolerated in Phase 1 and Phase 2 clinical trials to date. In a Phase 1b study it improved liver biomarkers, decreased liver stiffness and demonstrated a favorable PK and target engagement profile in patients with nonalcoholic fatty liver disease (NAFLD). Data from a completed Phase 2a liver fibrosis trial in nonalcoholic steatohepatitis (NASH) patients ([NCT05824156](#)) reported in 2023 showed consistent, positive improvements in key inflammatory and fibrogenesis-related biomarkers, including several that may serve as a potential bridge to activity in PSC. CM-101 has received Orphan Drug designation from the FDA and the EU's EMA, along with FDA Fast Track status.

About Primary Sclerosing Cholangitis

PSC is a rare, progressive liver disease, characterized by inflammation and fibrosis (scarring) of the bile ducts. Eventually, it can lead to cirrhosis of the liver and liver failure. PSC also increases the risk of various cancers, which account for about half of PSC deaths. PSC affects an estimated 30,000 patients in the U.S. and about 80,000 worldwide. The disease can occur in all ages, genders and races, but is more common in men and is typically diagnosed in patients in their 40s. The underlying cause of PSC is unknown, but about 75% of individuals with PSC also have inflammatory bowel disease. Currently there are no FDA or EMA-approved therapies for patients with PSC. Liver transplantation is common in advanced cases, but even then, PSC re-occurs in about 20% of transplanted patients. There is a high unmet need for therapeutic options to address the symptoms and modify the progression of this devastating illness.

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; the expectation that Chemomab will report topline data from the PSC clinical trial by mid-year 2024; the length, duration and impact of the war in Israel on Chemomab's business and operations; 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 those 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 as required by law.

About Chemomab Therapeutics Ltd.

Chemomab is a clinical stage biotechnology company developing innovative therapeutics for fibro-inflammatory diseases with high unmet need. Based on the unique and pivotal role of CCL24 in promoting fibrosis and inflammation, Chemomab developed CM-101, a monoclonal antibody that neutralizes CCL24 activity. In preclinical and clinical studies, CM-101 appears safe, with the potential to treat multiple severe and life-threatening fibro-inflammatory diseases. Chemomab has reported encouraging results from three clinical trials of CM-101 in patients, including a Phase 1b trial in NAFLD patients, a Phase 2a liver fibrosis trial in NASH patients and an investigator-initiated study in patients with severe lung injury. The CM-101 program for the treatment of systemic sclerosis is Phase 2-ready with an open U.S. IND. A Phase 2 trial in primary sclerosing cholangitis patients has completed patient enrollment, with topline data expected in midyear 2024. For more information about Chemomab, visit chemomab.com.

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