Chemomab Therapeutics Receives FDA Fast Track Designation for CM-101 for the Treatment of Primary Sclerosing Cholangitis

—CM-101's Unique Dual Anti-Fibrotic and Anti-Inflammatory Activity Has Disease Modifying Potential in this Poorly Treated Condition—

—CM-101's Phase 2 SPRING Trial in PSC is Advancing Towards Completion of Enrollment with Top-line Readout Expected in 2H 2024—

TEL AVIV, Israel, Nov. 15, 2023 /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 that the U.S. Food and Drug Administration (FDA) has granted CM-101 Fast Track designation for the treatment in adult patients of primary sclerosing cholangitis (PSC), a fibrotic liver disease that can result in liver transplant, cancer and early death.

Fast Track is a process developed by the FDA to facilitate and expedite the development of new treatments that demonstrate a potential to address unmet medical needs in serious or life-threatening conditions. Programs with Fast Track designation can benefit from early and more frequent interactions with the FDA during the clinical development process. Therapeutic candidates with Fast Track designation may also be eligible for priority review and accelerated approval if supported by clinical data.

"This FDA Fast Track designation is an important validation of CM-101's potential to have a major impact on this devastating disease that attacks people in their prime years and lacks any approved treatments," said Adi Mor, PhD, co-founder, Chief Executive Officer and Chief Scientific Officer of Chemomab. "We designed the CM-101 Phase 2 SPRING trial to be supportive of a registrational trial in patients with PSC, and we welcome the enhanced opportunities for working closely with the FDA and for acceleration of the development and review process provided by Fast Track status."

There are no FDA-approved treatments for PSC. 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, which is designed to break the vicious cycle driving these pathways, has demonstrated the potential for disease modifying activity in preclinical and early clinical studies of PSC-related processes.

Chemomab Chief Medical Officer Matt Frankel, MD, added, "Promising biomarker and elastography results from our Phase 2a liver fibrosis study in nonalcoholic steatohepatitis (NASH) patients reported earlier this year reinforced our optimism about the therapeutic potential of CM-101. There are common fibrosis pathways in NASH and PSC, and CM-101's relevance to PSC is supported by extensive preclinical and patient sample studies. We also are encouraged by robust patient enrollment in the SPRING trial, which speaks to the high unmet need experienced by these patients. We look forward to continuing our work with PSC patients, their clinicians and the FDA to expedite advancement of CM-101 as a potential treatment for this terrible disease."

Chemomab's Phase 2 SPRING trial (NCT04595825) is a double-blind, placebo-controlled study assessing the safety and tolerability of CM-101 in PSC patients. The trial is also measuring a wide range of relevant biomarkers and physiological parameters. Patient enrollment in the trial is advancing towards completion and Chemomab anticipates reporting a top-line readout in the second half of 2024.

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 NASH patients (NCT05824156) reported earlier this year 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 Orphan Drug designation from the FDA and Europe's EMA and is currently being evaluated in PSC patients in the Phase 2 SPRING trial.

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 transplant 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 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 designed to neutralize 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 and a Phase 2 trial in primary sclerosing cholangitis patients is ongoing, with top-line data expected in the second half of 2024. For more information about Chemomab, visit chemomab.com.

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