Chemomab Announces FDA Clearance of Its IND Application for CM-101, a First-In-Class CCL24 Neutralizing Antibody for the Treatment of Primary Sclerosing Cholangitis

--First U.S. IND Enables Increase in the Number of Clinical Sites for Chemomab's Ongoing Phase 2 SPRING Trial--

--Initiation of U.S. Trials in Line with Announced Corporate Strategy to Expand the Company's Clinical and Commercial Presence in the U.S.--

TEL AVIV, Israel, Dec. 2, 2021 /PRNewswire/ -- Chemomab Therapeutics, Ltd. (Nasdaq: CMMB) (Chemomab), a clinical-stage biotech company focused on the discovery and development of innovative therapeutics for fibrotic and inflammatory diseases with high unmet need, today announced that the U.S. Food and Drug Administration ("FDA") has cleared the company's Investigational New Drug ("IND") application for CM-101, a first-in-class CCL24-neutralizing antibody for the treatment of the rare disease primary sclerosing cholangitis (PSC). The Phase 2 SPRING trial assessing CM-101 as a potential treatment for PSC is already underway in Europe and Israel and is now being expanded to include U.S. sites.

"FDA clearance of the IND for our first U.S. clinical trial is an important milestone for Chemomab," said Adi Mor, PhD, co-founder and Chief Scientific Officer of Chemomab. "This clearance allows us to significantly increase the number of clinical sites in our Phase 2 SPRING study, as we augment our development capabilities and expand our clinical and business presence in the U.S."

Chemomab's SPRING trial is a Phase 2 multicenter, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of CM-101 over 15 weeks of treatment in patients with PSC. The trial will include clinical sites in the U.S., U.K., E.U. and Israel. The initial clinical readout is expected in 2022.

For more information on the SPRING trial in primary sclerosing cholangitis, see ClinicalTrials.gov using the identifier: NCT04595825.

About CM-101

Chemomab's lead clinical candidate, CM-101, is a first-in-class monoclonal antibody targeting the soluble protein CCL24, a novel and differentiated target that is overexpressed in fibrotic tissues. In preclinical studies CCL24 has been shown to play a unique and pivotal role in promoting fibrosis and inflammation, inducing a dual effect that includes the direct activation of fibroblasts and recruitment of inflammatory cells to damaged tissues. CM-101 has been shown to substantially attenuate fibrosis and inflammation across a wide range of *in vitro* and *in vivo* models, including experimental models of primary sclerosing cholangitis, systemic sclerosis, idiopathic pulmonary fibrosis and nonalcoholic steatohepatitis.

CM-101 appeared safe and well-tolerated in Phase 1a and 1b clinical studies in healthy volunteers and non-alcoholic fatty liver disease (NAFLD) patients. It is currently being assessed in the Phase 2 SPRING trial in PSC and in a Phase 2 liver fibrosis study. A third Phase 2 trial in systemic sclerosis is expected to begin in early 2022.

About Primary Sclerosing Cholangitis

Primary sclerosing cholangitis is a rare and serious disease of the bile ducts in the liver. An estimated 30,000 people in the U.S. alone have the condition. In PSC, inflammation eventually leads to fibrosis, or scarring, of the bile ducts and the liver. These scars make the ducts hard and narrow and gradually cause serious liver damage. The majority of people with PSC also have inflammatory bowel disease. The exact cause of PSC is unknown, but an autoimmune-fibrotic mechanism may play an important role. PSC typically progresses slowly but it can eventually lead to repeated infections, liver failure and cancers of the bile duct, liver or colon. There are no approved therapies for PSC—care focuses on managing symptoms and, when possible, temporarily opening blocked bile ducts. A liver transplant is the only known intervention with curative potential for advanced PSC, but the disease may recur in the transplanted liver in some patients.

About Chemomab Therapeutics Ltd.

Chemomab is a clinical-stage biotech 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. It is currently in two Phase 2 safety and efficacy trials—one in patients with primary sclerosing cholangitis and the second in patients with liver fibrosis, with a third Phase 2 trial in systemic sclerosis expected to begin early in 2022.

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; 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: 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; 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.

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