

Chemomab Announces FDA Clearance of Investigational New Drug Application for Phase 2 Clinical Trial of CM-101 in Patients with Systemic Sclerosis

—ABATE Phase 2 Trial Aims to Further Assess Safety and Establish Biological and Clinical Proof-of-Concept for CM-101 as a Potential Treatment for Patients with Systemic Sclerosis —

TEL AVIV, Israel, Feb. 21, 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 U.S. Food and Drug Administration (FDA) clearance of the company's Investigational New Drug (IND) Application to evaluate CM-101 in a Phase 2 trial in adults with systemic sclerosis (SSc).

CM-101 is a first-in-class monoclonal antibody designed to interfere with key biological pathways associated with SSc and other serious fibro-inflammatory diseases. In preclinical studies, CM-101 reduced inflammatory and fibrotic injury to the lung, skin and vasculature—organ systems often affected in SSc patients. In early clinical trials, CM-101 was well-tolerated, reducing fibrogenesis-related biomarkers and demonstrating anti-inflammatory effects in patients with severe lung inflammation, non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). CM-101 has been granted Orphan Drug designation by the FDA for SSc and for primary sclerosing cholangitis (PSC), a rare liver disease. The CM-101 Phase 2 SPRING trial in PSC patients is currently ongoing.

Matt Frankel, MD, Chief Medical Officer of Chemomab, said, "Achieving FDA clearance to initiate our Phase 2 systemic sclerosis trial is an important milestone for Chemomab. We are encouraged by the results of recent clinical studies of CM-101 in COVID patients with SSc-like acute lung injury and in NASH patients, which showed consistent trends in reducing multiple biomarkers associated with fibro-inflammatory disease. We believe that CM-101 has the potential to become the first disease-modifying treatment for this debilitating condition that is thought to be the most lethal of the systemic rheumatic disorders. We look forward to initiating patient enrollment in the first half of this year."

Francesco Del Galdo, MD, PhD, Professor of Experimental Medicine at the University of Leeds in the U.K. and Head of the Scleroderma Programme at the Leeds Institute of Rheumatic and Musculoskeletal Medicine, is the Principal Investigator of the Chemomab systemic sclerosis trial.

Professor Del Galdo noted, "Preclinical studies conducted by me and my colleagues show that CCL24, the disease target of CM-101, appears to be a key driver of the immune-driven fibrosis affecting tissues including the lung, skin and blood vessels that are key aspects of SSc pathology. Our patients and we, as their physicians, urgently need an effective therapy able to treat the multiple manifestations of scleroderma. I welcome the opportunity to help launch and coordinate this innovative clinical trial for patients with SSc in the U.S., Europe and Israel, scheduled to open later this year."

About the CM-101 Phase 2 Systemic Sclerosis Study and the ABATE Trial

The ABATE trial (a Phase 2, multicenter, randomized, double-blind, proof-of-biology study to evaluate the Safety, Tolerability, and Activity of CM-101 in Patients with Systemic Sclerosis) will enroll 45 patients with clinically active dermatologic, vascular or pulmonary SSc. The study population is expected to be roughly split between patients with diffuse cutaneous SSc and patients with limited SSc. The trial is designed to further assess safety and establish biological and clinical proof-of-concept for CM-101 as a potential treatment for patients with SSc. The primary outcome measure is safety. Secondary endpoints include multiple serum-based biological markers and a variety of exploratory biological and clinical outcomes, including the American College of Rheumatology Composite Response Index in Systemic Sclerosis (ACR-CRISS) score and its revisions (rCRISS). The trial includes a 24-week double blind period during which active treatment patients will receive 10 mg/kg of CM-101 by intravenous infusion every three weeks, followed by a 24-week open label extension, where all patients will receive a 10 mg/kg dose. The trial also includes multiple clinical assessments of the skin, vasculature and pulmonary function. It is expected to generate additional information about disease mechanisms, provide data relevant to future patient stratification strategies and inform the selection of appropriate endpoints for future studies. A top-line data read-out is planned for the second half of 2024.

About Systemic Sclerosis

Systemic sclerosis, also known as scleroderma, is a rare autoimmune rheumatic disease characterized by fibrosis and inflammation of the skin, joints and internal organs, as well as vascular abnormalities. It predominantly affects women and is typically diagnosed when patients are between 30 and 50 years old. It is considered the most lethal of the systemic rheumatic diseases with a median survival of only 10 years. There is no approved disease-modifying drug for the disease. Current estimates from the Scleroderma Foundation suggest there are approximately 100,000 systemic sclerosis patients in the U.S.

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. Extensive preclinical data showing the unique and pivotal role of the soluble protein CCL24 in promoting fibrosis and inflammation led Chemomab to develop 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 in the first half of 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 potential for CM-101 to treat SSc; risks associated with data interpretation, whether the regulatory authority will agree with our interpretation, and whether earlier preclinical and/or clinical data are predictive of the results of future trials or studies; risks concerning the future operations of Chemomab and its ability to successfully initiate and complete clinical trials and achieve regulatory milestones; and the commercial potential and potential benefits of any product candidates. Any statements contained in this communication that are not statements of historical fact may be deemed to be forward-looking statements. 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 press release, including: risks related to Chemomab's ability to effectively implement its clinical strategy and its ability to achieve the anticipated results; 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 commercialize its product candidates; 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 with the SEC. Chemomab expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except to the extent required by applicable law.

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