# Chemomab Reports Positive Feedback From Two Recent FDA Meetings Supporting Phase 3 Advancement of Nebokitug in Primary Sclerosing Cholangitis

*—Achieves FDA Alignment on CMC and Non-Clinical Toxicology Regulatory Path for Nebokitug in PSC—*

*—Preparations for the Nebokitug PSC Phase 3 Clinical Trial Advance as Discussions with Potential Strategic Partners Continue—*

**TEL AVIV, Israel, June 11, 2025** -- Chemomab Therapeutics Ltd., (Nasdaq: CMMB), a clinical stage biotechnology company developing innovative therapeutics for fibro-inflammatory diseases with high unmet need, today reported that it has obtained confirmation from the FDA on two significant development milestones as the company continues to finalize the nebokitug Phase 3 program.

As part of the FDA End-of-Phase 2 (EOP2) review process, Chemomab and the FDA addressed multiple Chemistry, Manufacturing, and Controls (CMC) topics critical to ensuring the quality and consistency of drug supply for the late-stage development and eventual commercialization of nebokitug. Following productive discussions, the FDA indicated agreement with the CMC strategy proposed by Chemomab and its contract manufacturing partner.

Chemomab also engaged in  a Type C meeting with the FDA to address the non-clinical fetal and embryo developmental toxicology studies that are part of the new drug regulatory pathway. Importantly, the FDA agreed that this toxicology testing may be conducted in parallel with the nebokitug Phase 3 clinical trial and be submitted as part of the planned Biologics Licensing Application (BLA). This represents a favorable outcome for Chemomab, and the FDA's flexibility supports the timely advancement of the program.

Adi Mor, PhD, co-founder, Chief Executive Officer and Chief Scientific Officer of Chemomab, commented, "Following up on our positive and constructive interactions with the FDA in December regarding the design of the proposed nebokitug PSC Phase 3 pivotal trial, we have further aligned on two additional significant milestones–CMC requirements needed for manufacturing of drug supply for the "to be marketed" formulation and the timing of non-clinical toxicology testing. We look forward to continuing to work closely with the FDA as we finalize the details of the proposed Phase 3 development program and continue our discussions with potential strategic partners."

**About Nebokitug**

Nebokitug (CM-101) is a first-in-class dual activity monoclonal antibody that neutralizes CCL24, a soluble protein that helps drive the inflammatory and fibrotic pathways central to primary sclerosing cholangitis (PSC) and other fibro-inflammatory diseases. By inhibiting CCL24, nebokitug blocks immune cell recruitment and fibroblast activation, thereby interrupting the self-reinforcing cycle that results in fibrosis. In clinical and preclinical studies, nebokitug has been shown to have a favorable safety profile, with the potential to treat multiple severe and life-threatening fibro-inflammatory diseases. Chemomab has reported positive results from four clinical trials of nebokitug in patients, including the Phase 2 SPRING trial in patients with PSC. This study achieved the primary safety endpoint and nebokitug-treated patients with moderate/advanced disease showed improvements on a wide range of disease-related secondary endpoints. The results of the Open Label Extension portion of the SPRING trial, where PSC patients received nebokitug for up to a total of 48 weeks, confirmed and extended the initial Phase 2 results. Nebokitug has received FDA and EMA Orphan Drug designations for the treatment of PSC and systemic sclerosis and FDA Fast Track status for the treatment of PSC in adults.

**Forward-Looking Statement**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "estimate," "intend," "may," "plan," "potentially," "will" or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: the risk that certain acknowledgements from the End-of-Phase 2 (EOP2) meeting with the FDA in connection with PSC regulatory approval may not materialize into a pathway for regulatory approval; that certain conclusions and assumptions drawn from the EOP2 meeting with the FDA discussed in the press release may prove incorrect and adversely affect the ability for nebokitug to become an FDA fully approved therapy; the risk that the full data set from the nebokitug study or data generated in further clinical trials of nebokitug may not be consistent with the results of the nebokitug Phase 2 PSC trial; failure to obtain, or delays in obtaining, regulatory approvals for nebokitug in the U.S., Europe or other territories; failure to successfully commercialize nebokitug, if approved by applicable regulatory authorities, in the U.S., Europe or other territories, or to maintain U.S., European or other territory regulatory approval for nebokitug if approved; uncertainties in the degree of market acceptance of nebokitug by physicians, patients, third-party payors and others in the healthcare community; development of unexpected safety or efficacy concerns related to nebokitug; failure to successfully conduct future clinical trials for nebokitug, including due to the Company's potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval, among other things; risks that the Company's clinical studies will be delayed or that serious side effects will be identified during drug development; failure of third parties on which the Company is dependent to manufacture sufficient quantities of nebokitug for commercial or clinical needs, to conduct the Company's clinical trials; changes in laws and regulations applicable to the Company's business and failure to comply with such laws and regulations; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; and uncertainties with respect to the Company's need and ability to access future capital; and the intensity and duration of the current war in Israel, and its impact on our operations in Israel. These risks are not exhaustive. You should carefully consider the risks and

uncertainties described in the “Risk Factors” sections of our 20-F for the year ended December 31, 2024. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this press release. Before you invest, you should read the documents we have filed and will file with the SEC for more complete information about us. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov. This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities law of any such state or jurisdiction.

**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 role of the soluble protein CCL24 in promoting fibrosis and inflammation,Chemomab developed nebokitug (CM-101), a first-in-class dual activity monoclonal antibody that neutralizes CCL24 and has demonstrated disease-modifying potential. In clinical and preclinical studies, nebokitug has been shown to have a favorable safety profile and has been generally well-tolerated, with the potential to treat multiple severe and life-threatening fibro-inflammatory diseases. Chemomab has reported positive results from four clinical trials of nebokitug in patients. Based on positive data from its Phase 2 SPRING trial in primary sclerosing cholangitis (PSC), the company is preparing for potential initiation of a nebokitug PSC Phase 3 trial. The design of Phase 3 calls for a single pivotal trial based on a clinical event primary endpoint that provides a clear and streamlined pathway to potential full regulatory approval. Nebokitug has received FDA and EMA Orphan Drug and FDA Fast Track designations for the treatment of PSC. Chemomab’s nebokitug program for the treatment of systemic sclerosis has an open U.S. IND. For more information, visit: chemomab.com.

**Contact:**

**Media and Investors:**

Barbara Lindheim

Consulting Vice President, Investor & Public Relations, Strategic Communications

Phone: +1 917-355-9234

barbara.lindheim@chemomab.com

IR@chemomab.com