Chemomab Therapeutics Announces Third Quarter 2022 Financial Results and Provides Corporate Update

–Chemomab to Host Conference Call for Investors Today, November 11 at 8:00 am ET–

TEL AVIV, Israel, Nov. 11, 2022 /PRNewswire/ -- Chemomab Therapeutics, Ltd. (Nasdaq: CMMB), a clinical-stage biotechnology company focused on the discovery and development of innovative therapeutics for fibrotic and inflammatory diseases with high unmet need, today announced financial and operating results for the third quarter ended September 30, 2022 and provided a corporate update.

"We continued to make good progress in advancing our clinical programs for CM-101 during the third quarter," said Dale Pfost, PhD, Chief Executive Officer of Chemomab. "We have been preparing to report the results of our liver fibrosis biomarker trial in NASH patients in the coming weeks, while continuing to implement the expansion of our Phase 2 trial in primary sclerosing cholangitis, or PSC. Activities included opening additional clinical sites in the U.S. and Europe and filing regulatory submissions for the dose-finding cohorts and open label extension we are adding. We also are ramping up recruitment activities with patients and physicians to ensure enrollment is on-track. Importantly, during the quarter we wrapped up the design process for our upcoming Phase 2 trial in systemic sclerosis, or SSc. We are very pleased with the design, which was developed with input from a number of systemic sclerosis experts. In this trial we seek to confirm the critical role of CCL24 in SSc, and to generate data that can establish biological and clinical proof of concept for CM-101. The study should also enable us to identify the optimal patient population for CM-101 and to inform the selection of appropriate endpoints for subsequent trials. We anticipate launching the new trial around year-end and enrolling the first patients early in 2023."

Dr. Pfost continued, "In support of our ongoing efforts to educate the scientific and medical communities about the critical role of CCL24 and CM-101 in fibro-inflammatory diseases, our researchers made presentations at important scientific meetings during the quarter. A poster at the recent AASLD Liver Meeting presented new preclinical data supporting the key role of CCL24 in the pathophysiology of PSC and showing how CM-101 can interfere with these disease processes. A featured presentation at the Anti-Fibrosis Drug Development Summit highlighted how Chemomab has used biomarkers as a strategic translational tool to inform and de-risk our drug development programs. A third presentation at an international conference on lung health unveiled new clinical data from an investigator-initiated open label study assessing CM-101 in COVID patients with acute lung injury. It showed that CM-101 administration was well tolerated and was associated with decreases in inflammatory and fibrogenic biomarkers that are also relevant in other fibro-inflammatory diseases like systemic sclerosis. This is an excellent example of the types of data we also hope to see in the liver fibrosis biomarker study that we are looking forward to reporting later this year."

Clinical Update

Phase 2 Liver Fibrosis Trial in NASH patients
Chemomab has concluded the treatment phase of its randomized, placebo-controlled Phase 2 liver fibrosis trial in NASH patients. Preparations for a planned topline read-out continued in the third quarter. The main study outcome is safety and tolerability, with secondary outcomes including a variety of biomarkers associated with inflammation and fibrosis. These may provide useful insights in support of the overall CM-101 clinical development program and should also generate the pharmacokinetic and tolerability data needed to inform next steps in the development of the current subcutaneous formulation of CM-101. The company is on-track to report study results before year-end.

Phase 2 Trial in Primary Sclerosing Cholangitis patients
The company has been adding additional clinical sites, along with an open label extension and a dose finding component intended to inform selection of the optimal dose of CM-101 to advance in later development. Global regulatory filings supporting these changes are proceeding, with a number of new sites in Europe and the U.S. now open. An interim Drug Monitoring Committee safety review of the current PSC cohort is targeted for later this year. Additionally, a number of outreach and education initiatives have been implemented to support ongoing patient recruitment.

Phase 2 Trial in Systemic Sclerosis patients
Chemomab has completed the design of its upcoming Phase 2 trial in systemic sclerosis. The company aims to establish biological proof of concept for clinically relevant aspects of this complex disease, focusing on CM-101's potential activity in modifying the skin, lung and vascular pathophysiology observed in SSc patients. To that end, we will enrich the study with SSc patients who have higher levels of CCL24 and may therefore be more likely to respond to neutralization of this critical chemokine.

Key design elements include the following:

- The trial is a randomized, double-blind, placebo-controlled study that will enroll sixty (60) SSc patients.
- To be eligible for the study, patients must manifest two key characteristics: the presence of clinically active disease, either dermatologic or pulmonary, and high serum levels of circulating CCL24.
- Forty (40) patients will be randomized to treatment with CM-101 and twenty (20) will be randomized to placebo.
- Of the 40 patients on active treatment, approximately half will have limited SSc, and half will have diffuse cutaneous disease.
- The study includes a 24-week double blind period during which patients assigned to active treatment will receive

CM-101 at a dose of 10 mg/kg, via intravenous infusion, every three weeks.
- Following the double-blind period, patients will enter a 24-week open label treatment period, where all patients will receive CM-101 at a dose of 20 mg/kg via intravenous infusion every three weeks.
- All patients enrolled will undergo a skin biopsy at baseline and again after the double-blind treatment period, along with multiple clinical assessments of skin, vascular and pulmonary function.
- The primary outcome measure for the trial will be demonstration of the safety and tolerability of treatment with CM-101.
- All other outcome measures will be principally assessed as changes from baseline to the end of the double-blind treatment period.

The secondary outcome measures of the trial are focused on highly relevant and informative biological read-outs. Key secondary outcomes include:

- Evaluation of multiple serum-based biological markers that are known to be associated with different manifestations of SSc including:
  - Inflammatory cytokines (such a CCL2, IL6 and CXCL10)
  - Vascular and growth factor-related biomarkers (such as VEGF and PDGF)
  - Pulmonary-related biomarkers (such as KL-6, SPD and CCL18), and
  - Fibrogenesis and extracellular matrix biomarkers (collagens, MMPs and ELF score).
- Inflammatory, fibrotic and target expression markers in skin biopsies, including but not limited to CCL24 and CCR3 expression levels.
- Pharmacokinetics and target engagement of CM-101.
- Monitoring for the presence of any potential anti-drug antibodies during the study.

Exploratory **biological outcomes** assessments will include immune cell phenotyping, assessments of neutrophil function, and ex-vivo biological assays.

Exploratory **clinical outcomes** will include evaluation of:

- Vascular involvement, using nail fold capillaroscopy, vascular imaging and digital ulcer burden
- Skin involvement using modified Rodnan scoring
- Pulmonary disease involvement using pulmonary function tests, and
- Multiple patient-reported outcome measures.

The data collected should also enable us to evaluate global effects of intervention with CM-101 using the revised CRISS scale.

We intend to conduct this study at multiple sites in the U.S., the E.U. and Israel. We are currently finalizing the required regulatory documents and we intend to file an Investigational New Drug application with the U.S. Food and Drug Administration in the coming weeks.

Recent Highlights

- At the **American Association for the Study of Liver Disease (AASLD) Liver Meeting® 2022**, Chemomab presented a poster, *CCL24 Blockade Attenuates Biliary Inflammation by Interfering with Monocyte and Neutrophil Recruitment*, that reinforces the key role of CCL24 in the pathophysiology of primary sclerosing cholangitis. Using two in-vivo models for immune cell trafficking, Chemomab researchers demonstrated that CCL24 plays a critical role in the recruitment and migration of monocytes and neutrophils, which are major players in PSC pathophysiology. Chemomab's CM-101, a first-in-class CCL24 neutralizing monoclonal antibody, demonstrated an anti-inflammatory effect by interfering with migration of these cells to the damaged biliary area in an animal model of PSC. This study adds to the growing body of evidence validating CCL24 as a target for PSC and confirming the therapeutic potential of Chemomab's CCL24-neutralizing antibody.
- At the **Union World Conference on Lung Health 2022**, Chemomab CSO Adi Mor presented *Treatment with CM-101 Reduced Inflammatory & Fibrotic Biomarkers in Patients with COVID-19-Derived Lung Damage*, unveiling promising clinical data from an investigator-initiated open label clinical study showing that a single 10 mg/kg dose of CM-101 reduced biomarkers of lung inflammation and fibrogenesis in hospitalized COVID patients with serious lung involvement. Some of the mechanisms underlying lung inflammation resulting from COVID-19 infection are similar to those seen in chronic diseases that involve lung inflammation and fibrosis. The objective of the study was to assess the safety and activity of CM-101, including its impact on biomarkers related to lung inflammation and systemic sclerosis. CM-101 was well tolerated and demonstrated activity on these key biomarkers of inflammation and fibrogenesis that are relevant for systemic sclerosis and other fibro-inflammatory diseases.
- At the **Sixth Anti-Fibrotic Drug Development Summit** in Boston, Dr. Mor was a featured speaker, highlighting the growing use of inflammatory and fibrotic biomarkers to inform clinical trial design and de-risk drug development. In her presentation, *Crossing the Divide: Leveraging Fibrosis-Inflammatory Biomarkers to Inform Clinical Trial Design*, Dr. Mor showed how Chemomab has strategically used biomarkers throughout the drug discovery and development process as a key translational tool for competitive advantage, and how the company is continuing to use them today.

Third Quarter 2022 Financial Highlights

- **Cash Position:** Cash and cash equivalents were $46.5 million as of September 30, 2022, compared to $51.8 million as of June 30, 2022. The Company currently expects its runway to last through year-end 2023.
- **Research and Development (R&D) Expenses:** R&D expenses were $5.4 million for the third quarter ended September 30, 2022, compared to $1.5 million for the same quarter in 2021. The increase in R&D expense year-over-year primarily reflects the increase in activities in support of the company's preclinical and clinical programs.
- **General and Administrative (G&A) Expenses**: G&A expenses were $2.9 million for the third quarter ended September 30, 2022, compared to $1.4 million for the same quarter in 2021. The increase was primarily due to increases in salaries and related benefits expenses mainly related to key additions to the senior management team, as well as an increase in non-cash share-based expenses.
- **Net Loss**: Net loss was $8.1 million, or a net loss of approximately $0.035 per basic and diluted share, for the third quarter ended September 30, 2022, compared to $3.0 million, or a net loss of approximately $0.013 per basic and diluted share, for the quarter ended September 30, 2021.

The weighted average number of ordinary shares outstanding, basic and diluted were 228,773,418 (equal to 11,438,671 American Depository Shares) and 228,349,115 (equal to 11,417,456 American Depository Shares) for the quarters ended September 30, 2022, and September 30, 2021, respectively.

For further details on Chemomab's financial results for the quarter ended September 30, 2022, refer to the Form 10-Q, which was filed with the SEC on November 10, 2022.

Conference Call
Chemomab management will host a conference call for investors today, Friday, November 11, 2022, beginning at 8:00 a.m. Eastern Time to discuss these results and answer questions. Shareholders and other interested parties may access the live webcast or replay at Webcast link or at Chemomab's website at https://investors.chemomab.com/events, or by dialing +1 877-407-9208 (in the U.S.) or +1 201-493-6784 (outside the U.S. and in Israel) and entering passcode 13732524. Upon dialing in, please request the Chemomab conference call.

A replay of the call will be available on Chemomab's website for 90 days at www.chemomab.com.

About Chemomab Therapeutics Ltd.
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. 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 Phase 2 trials for primary sclerosing cholangitis and liver fibrosis, with a Phase 2 trial in systemic sclerosis expected to open around year-end, with first patients enrolled in early 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; 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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Condensed Consolidated Balance Sheets
In USD thousands (except share amounts)

Assets	**September 30, 2022 Unaudited**	**December 31, 2021 Audited**
Current assets		
Cash and cash equivalents	**10,741**	15,186
Short term bank deposits	**35,725**	45,975
Other receivables and prepaid expenses	**2,259**	1,527
Total current assets	**48,725**	62,688
Non-current assets		
Long term prepaid expenses	**776**	908
Property and equipment, net	**380**	357
Restricted cash	**77**	55
Operating lease right-of-use assets	**261**	345
Total non-current assets	**1,494**	1,665
Total assets	**50,219**	64,353
Current liabilities		
Trade payables	**1,247**	1,336
Accrued expenses	**2,577**	555
Employee and related expenses	**1,527**	653
Operating lease liabilities	**126**	106
Total current liabilities	**5,477**	2,650
Non-current liabilities		
Operating lease liabilities - long term	**118**	237
Total non-current liabilities	**118**	237
Commitments and contingent liabilities		
Total liabilities	**5,595**	2,887
Shareholders' equity		
Ordinary shares no par value - Authorized: 650,000,000 shares as of September 30, 2022 and as of December 31, 2021; Issued and outstanding: 229,015,402 ordinary shares as of September 30, 2022 and 228,090,300 as of December 31, 2021 (*)	**-**	-
Additional paid in capital	**100,171**	97,639
Accumulated deficit	**(55,547)**	(36,173)
Total shareholders' equity	**44,624**	61,466
Total liabilities and shareholders' equity	**50,219**	64,353

(*) 20 Ordinary Shares are equal to 1 American Depositary Share (ADS).

Condensed Consolidated Interim Statements of Operations (Unaudited)

In USD thousands (except share amounts)

	Three months Ended September 30, 2022	Three months Ended September 30, 2021	Nine months Ended September 30, 2022	Nine months Ended September 30, 2021
Operating expenses				
Research and development	**5,423**	1,487	**11,082**	3,951
General and administrative	**2,894**	1,404	**8,809**	3,392
Total operating expenses	**8,317**	2,891	**19,891**	7,343
Financing expense (income), net	**(237)**	77	**27**	99
Loss before taxes	**8,080**	2,968	**19,918**	7,442
Taxes on income (benefit)	**-**	-	**(544)**	-
Net loss for the period	**8,080**	2,968	**19,374**	7,442
Basic and diluted loss per Ordinary Share (*) (**)	**0.035**	0.013	**0.085**	0.03
Weighted average number of Ordinary Shares outstanding, basic, and diluted (*) (**)	**228,773,418**	227,956,060	**228,349,115**	195,292,384

(*) Number of shares has been retroactively adjusted to reflect the share reverse split effected on March 16, 2021 (refer to Note 1B).
(**) 20 Ordinary Shares are equal to 1 American Depositary Share (ADS).

SOURCE Chemomab Therapeutics, Ltd.