Chemomab Therapeutics Reports Positive Data from Secondary Analysis of Phase 2a Liver Fibrosis Trial in NASH Patients at EASL 2023

–Treatment with CM-101 Improves Additional Biomarkers of Fibrosis and Inflammation, `Reinforcing and Extending Initial Study Results–

–Provides New Insights into CM-101 Activity in NASH Patients at Greater Risk of Progressive Disease, Providing Further Support for CM-101's Direct Anti-inflammatory and Anti-fibrotic Dual Mode of Action–

–Demonstrates Improvements in Key Biomarkers Associated with Other Fibrotic Liver Diseases Including Primary Sclerosing Cholangitis–

TEL AVIV, Israel, June 21, 2023 /PRNewswire/ -- Chemomab Therapeutics Ltd. (Nasdaq: CMMB), (Chemomab), a clinical stage biotechnology company developing innovative therapeutics for fibro-inflammatory diseases with high unmet need, today reported topline results from secondary analyses of its Phase 2a liver fibrosis trial assessing CM-101, its first-in-class CCL24-neutralizing antibody, in patients with non-alcoholic steatohepatitis (NASH). The results were included in a late-breaking poster presentation at the 2023 EASL Congress in Vienna, Austria.[1]

Overall, the data showed improvements across an additional set of inflammatory and fibrotic biomarkers that are consistent with the positive clinical results Chemomab released in January. Additionally, in NASH patients at greater risk of disease progression, CM-101 treatment resulted in a greater biomarker response than in NASH patients with lower risk disease or in placebo-treated patients.

Adi Mor, PhD, Chemomab co-founder, CEO and CSO, commented, "These additional analyses of our liver fibrosis data in NASH patients are very encouraging. They supplement and extend our initial data results, showing a consistent pattern of improvement in CM-101-treated patients in biomarkers associated with fibrogenesis and inflammation. We are especially pleased to see that CM-101 treated-patients with higher FAST scores—those at greater risk of progressive disease—tended to demonstrate greater biomarker improvements than those with lower FAST scores. Additionally, we consider these data to be highly relevant to our ongoing CM-101 Phase 2 trial in primary sclerosing cholangitis (PSC), demonstrating improvements in biomarkers that are also associated with the inflammation and fibrogenesis found in PSC patients. Notably, our PSC trial involves the evaluation of significantly higher doses of CM-101, with patient dose cohorts of 10mg/kg and 20mg/kg administered intravenously, compared to the liver fibrosis study in NASH patients, which used a subcutaneous dose of 5mg/kg."

The new analyses assessed additional biomarkers and also used the FibroScan-AST (FAST) score to categorize study patients based on progressive disease risk, thereby enabling the evaluation of CM-101 activity in the main target population of patients with more active disease.[2] FAST is a validated score composed of non-invasive FibroScan ® and AST measurements that is used to identify patients with a high risk of NASH progression.[3] The results showed that:

- FAST scores were improved in a higher proportion of CM-101-treated patients than in placebo patients.
- CM-101-treated patients with higher FAST scores demonstrated greater improvements in key fibro-inflammatory biomarkers, such as Pro-C3, than patients with lower FAST scores or placebo patients.
- CM-101-treated patients with higher FAST scores showed improvements in several fibro-inflammatory biomarkers generally comparable to those achieved in several recent successful NASH clinical trials.

In these secondary analyses, CM-101-treated patients showed improvements in an additional set of biomarkers associated with active fibrosis and inflammation:

- FIB-4, an index for determining NASH status that includes age, platelet count, AST and ALT levels, was improved in CM-101-treated patients vs. placebo patients.
- AST/ALT ratio, a liver enzyme ratio, was improved in CM-101-treated patients vs. placebo patients.
- Neutrophil-to-Lymphocyte Ratio (NLR), an indicator of inflammation, was improved in CM-101-treated patients vs. placebo patients, and NLR was further improved in groups with higher FAST scores.
- PRO-C3, which captures active fibrogenesis and correlates with fibrotic disease severity, was improved in CM-101-treated patients vs. placebo patients and was further improved in groups with higher FAST scores. As an overall indicator of fibrogenesis and fibrotic disease, PRO-C3 is also considered a "bridge" to PSC and other anti-fibrotic indications.

Scott L. Friedman, MD, Dean for Therapeutic Discovery and Chief of the Division of Liver Diseases at the Icahn School of Medicine at Mount Sinai in New York City, is an expert on the fibrosis associated with chronic liver disease and a co-author of the EASL poster. Dr. Friedman noted, "It is encouraging that consistent positive improvements are seen across a range of fibro-inflammatory biomarkers in both CM-101 Phase 2a study analyses. The greater improvement in biomarkers in the higher FAST score-enriched subgroup provides further evidence of CM-101's potential to have a positive impact on fibrotic diseases such as NASH and PSC, whose pathophysiology may be associated with the dual fibro-inflammatory mechanism that CM-101 is intended to address."

In January, the company reported that the Phase 2a liver fibrosis trial met its primary endpoint of safety and tolerability and that CM-101 achieved reductions in secondary endpoints that included a range of liver fibrosis biomarkers and physiologic assessments. The EASL poster also summarized these results, including:

- CM-101 treatment demonstrated a favorable PK-target engagement profile.
- CM-101 treatment was associated with improvements in multiple fibrosis biomarkers and with a reduction in FibroScan liver stiffness stage.
- CM-101 treatment was associated with improvements in more than one liver fibrosis-related biomarker—almost 60% of CM-101 patients responded in at least three biomarkers, compared to no placebo patients.
- Higher levels at baseline of CM-101's target—the soluble chemokine CCL24—in CM-101-treated patients were associated with greater reductions in fibrosis-related biomarkers and a greater likelihood of being a multiple biomarker responder.

About the Phase 2 Liver Fibrosis Trial in NASH Patients
The randomized, placebo-controlled trial enrolled 23 NASH patients with stage F1c, F2 and F3 disease who were randomized to receive either CM-101 (14 patients) or placebo (9 patients). Patients received eight doses of 5 mg/kg of CM-101 or placebo, administered by subcutaneous (SC) injection once every two weeks, for a treatment period of 16 weeks. This trial was primarily designed to assess the safety and tolerability of the SC formulation of CM-101 and to evaluate the drug's impact on liver fibrosis biomarkers relevant to both NASH and other rare fibro-inflammatory conditions that are the focus for the company, such as primary sclerosing cholangitis. For more information on the initial trial results, click here.

1. Poster presentation: *Phase 2a study of CM-101, a CCL24 neutralizing antibody, in patients with nonalcoholic steatohepatitis: A proof- of-concept study* June 21-24, 2023, 9-17:00 CEST every day: Poster-Late-Breaker, LBP-28
2. NASH patients at risk for disease progression defined as FAST scores NAS≥4; F≥2.
3. Woreta TA, Van Natta ML, Lazo M, Krishnan A, Neuschwander-Tetri BA, Loomba R, et al. (2022) Validation of the accuracy of the FAST™ score for detecting patients with at-risk nonalcoholic steatohepatitis (NASH) in a North American cohort and comparison to other non-invasive algorithms. PLoS ONE 17(4): e0266859.

About Chemomab Therapeutics
Chemomab is a clinical stage biotechnology company discovering and developing innovative therapeutics for fibro-inflammatory diseases with high unmet need. Based on the unique and pivotal role of the chemokine CCL24 in promoting fibrosis and inflammation, Chemomab developed CM-101, a monoclonal antibody designed to neutralize CCL24 activity. In preclinical and clinical studies to date, CM-101 appears safe, with the potential to treat multiple severe and life-threatening fibro-inflammatory diseases. To date, Chemomab has reported encouraging results from three clinical trials, including a Phase 2 liver fibrosis trial in NASH patients and an investigator-initiated study in patients with severe lung injury. A Phase 2 trial in primary sclerosing cholangitis patients is ongoing, with topline data expected in the latter part of 2024. 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 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.

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