Chemomab Receives European Orphan Drug Designation for CM-101 for the Treatment of Primary Sclerosing Cholangitis

Tel Aviv -August, 2020 -- Chemomab Ltd., a clinical-stage biotech company focusing on discovery and development of innovative therapeutics for fibrosis-related diseases, today announces that the European Commission (EC) has granted Orphan Drug Designation (ODD) to its lead drug candidate CM-101 for the treatment of patients with Primary Sclerosing Cholangitis (PSC), based on a positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA). CM-101 holds ODD for the treatment of PSC from the US Food and Drug Administration (FDA). CM-101 is a CCL24 blocking monoclonal antibody that demonstrates amelioration of fibrosis and inflammation and is being developed as a potential treatment for patients with PSC.

“ODD is an important regulatory milestone in our global development plan for CM-101, which we believe has the potential to become a transformative treatment for patients living with PSC. Data from the phase 1 clinical trials of CM-101 have been encouraging and suggest that CM-101 is safe and capable of eliciting anti-fibrotic clinical benefit. We look forward to advancing CM-101 through our Phase 2a clinical trial planned to start during Q3 2020” said Dr. Adi Mor, Chief Executive Officer of Chemomab. “PSC has no approved disease modifying treatment, urgently necessitating the development of novel treatments to improve patients’ quality of life. We believe that this designation will maximize the potential to make this new treatment available for patients as quickly as possible” said Dr. Stephen Squinto, Chemomab’s Chairman of the Board.

“PSC Support, the patient organization for people with PSC, is encouraged by the EMA COMP’s decision to grant ODD to CM-101. It demonstrates regulatory support for advancing PSC medicine development to address the huge unmet needs of PSC patients, who urgently need an effective treatment to slow or stop progression of the disease" said Martine Walmsley, PSC support.

Orphan designations are important regulatory milestones that facilitate and accelerate the clinical development of drugs for rare diseases. The EMA grants orphan medicinal product designation to investigational drugs intended to treat, prevent or diagnose a life-threatening or chronically debilitating disease affecting fewer than five in 10,000 people in the EU and for which no satisfactory treatment is available or, if such treatment exists, the medicine must be of significant benefit to those affected by the condition. Orphan medicinal product designation provides regulatory and financial incentives for companies to develop and market therapies, including ten years of market exclusivity, protocol assistance, fee reductions and EU-funded research.

About PSC

Primary Sclerosing Cholangitis (PSC) is a chronic progressive cholestatic liver disease that is characterized by inflammation and fibrosis of the bile ducts. The pathological hallmarks of PSC include injury to the integrity of the biliary ducts, retention of bile acids and intrahepatic inflammation and fibrosis. Disease progression will eventually lead to liver failure with consequent complications such as portal hypertension and increased risk of malignancy. Males are affected twice as often as females and an estimated 70% of PSC patients have concomitant inflammatory bowel disease.

About Chemomab

Chemomab is a clinical-stage biotech company focusing on the discovery and development of innovative therapeutics for fibrosis-related diseases with high unmet need. Based on the unique and pivotal role of the soluble protein CCL24 in promoting fibrosis and inflammation, Chemomab generated CM-101 that is currently in

development for the treatment of patients with PSC, systemic sclerosis (SSc) and nonalcoholic steatohepatitis (NASH). During Q3 2020 Chemomab will initiate the first phase 2a clinical trial evaluating the safety and efficacy of CM-101 in subjects with PSC (SPRING Study).
Chemomab is a privately held company and is supported by strong lead investors that include OrbiMed and Thiel Capital.

About CM-101

Chemomab's CM-101 Platform is a first-in-class humanized monoclonal antibody designed to bind and block CCL24 activity. CM-101 interferes with the main pathologies that promote fibrosis and inflammation. It is highly effective in ameliorating fibrosis, as shown across multiple in-vivo, in-vitro and ex-vivo studies, including experimental models of liver, skin and lung fibrosis. CM-101 was found to be safe and well tolerated in phase 1 clinical trials and is currently under clinical development for PSC, SSc NASH. CM-101 hold orphan drug designation from the FDA and EMA for the treatment of PSC and SSc.

Chemomab Contact:

Mr. Sharon Elkobi
VP of Business Development
office@chemomab.com

+972-77-331-0156