January 17, 2023

Avalo Announces it Has Completed Targeted Enrollment of 80 Patients in Phase 2 PEAK Trial of AVTX-002 in Non-Eosinophilic Asthma

- Topline data expected in the second quarter of 2023

WAYNE, Pa. and ROCKVILLE, Md., Jan. 17, 2023 (GLOBE NEWSWIRE) -- Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced that it completed enrollment of the 80 patients targeted for the Phase 2 PEAK Trial evaluating AVTX-002 (anti-LIGHT mAb) in patients with Non-Eosinophilic Asthma (NEA). Avalo will allow additional patients currently in the run-in period to complete enrollment. Topline data from the clinical trial are expected to be released in the second quarter of 2023.

"We are very excited to have completed target enrollment in our Phase 2 PEAK Trial in patients with NEA. We believe the data readout will yield yet another clinical proof of concept for LIGHT inhibition in patients suffering from lung inflammation. We expect these trial results will add to the accumulating clinical evidence that cytokines regulated by decoy receptor 3 (DcR3): LIGHT (and its signaling network including BTLA), TL1A and FasL are key drivers of inflammatory diseases in the lung, gut and skin. We are eager to advance AVTX-002 in treating NEA, asthma broadly, and other dysregulated inflammatory disease," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board *"I thank the patients who have enrolled in the trial, the clinical investigators and the Avalo team who worked tirelessly to advance the trial to this point."*

The Phase 2 PEAK Trial is a randomized, double-blind, placebo-controlled, parallel group trial designed to evaluate the safety and efficacy of AVTX-002 for the treatment of poorly controlled NEA (NCT05288504). Following 12 weeks of treatment, the efficacy and safety of AVTX-002 will be evaluated compared with placebo. The primary endpoint is the proportion of patients who experience any of the following asthma-related events: (i) ≥6 additional reliever puffs of a short-acting beta-agonist (compared to baseline) in a 24-hour period on 2 consecutive days, or (ii) increase in inhaled corticosteroid dose ≥4 times than the dose at baseline, or (iii) a decrease in peak flow of 30% or more (compared to baseline) on 2 consecutive days of treatment, or (iv) an asthma exacerbation requiring the use of systemic corticosteroids (tablets, suspension, or injection) for at least 3 days, or (v) a hospitalization or emergency room visit because of an asthma exacerbation.

About AVTX-002

AVTX-002, Avalo's lead development asset, is a fully human monoclonal antibody (mAb),

directed against human LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with Herpes Virus **G**lycoprotein D for **H**erpesvirus Entry Mediator (HVEM), a receptor expressed by **T** lymphocytes). There is increasing evidence that the dysregulation of the LIGHT-signaling network which includes LIGHT, its receptors HVEM and LTβR and the downstream checkpoint BTLA, is a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders, including NEA. AVTX-002 previously demonstrated proof of concept in COVID-19 induced acute respiratory distress syndrome including reduction in mortality and respiratory failure.

About Avalo Therapeutics

Avalo Therapeutics is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT-signaling network.

LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin β receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator (BTLA), and CD160 (the LIGHT-signaling network). Accumulating evidence points to the dysregulation of the LIGHT network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

For more information about Avalo, please visit www.avalotx.com.

Forward-Looking Statements

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Avalo's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: timing and success of trial results and regulatory review; the development of product candidates or products; potential attributes and benefits of product candidates; the future financial and operational outlook; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; Avalo's debt and cash position and the need for it to raise additional capital in the near future; reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and the war in Ukraine; and those other risks detailed in Avalo's filings with the SEC. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any

forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

For media and investor inquiries

Christopher Sullivan, CFO
Avalo Therapeutics, Inc.
ir@avalotx.com
410-803-6793

or

Chris Brinzey
ICR Westwicke
Chris.brinzey@westwicke.com
339-970-2843

Source: Avalo Therapeutics