September 3, 2025

Artelo Biosciences Announces Positive Interim Phase 2 CAReS Results for the Treatment of Cancer Anorexia-Cachexia Syndrome (CACS)

Catalyst for Advancing Discussions with Pharmaceutical Companies that have Expressed Interest in ART27.13 for CACS

Consistent Improvements in Weight Gain, Lean Body Mass, and Activity were Observed Across Treated Patients including +6.4% Mean Weight Gain at 12 Weeks vs −5.4% Mean Weight Loss on Placebo

Safety Results Showed ART27.13 was Well Tolerated

SOLANA BEACH, Calif., Sept. 03, 2025 (GLOBE NEWSWIRE) -- Artelo Biosciences, Inc. **(Nasdaq: ARTL),** a clinical-stage pharmaceutical company focused on modulating lipid-signaling pathways to develop treatments for people living with cancer, pain, dermatologic, or neurological conditions, today announced highly encouraging interim results from its Phase 2 Cancer Appetite Recovery Study (CAReS) trial with ART27.13, the Company's peripherally acting cannabinoid receptor agonist for the treatment of cancer anorexia-cachexia syndrome (CACS). Affecting up to 80% of people living with cancer, CACS is marked by loss of appetite, weight loss, and breakdown of muscle and fat. This leading cause of death in cancer patients has no FDA-approved treatment. The CAReS interim data comparing ART27.13 to placebo supports acceleration of the Company's partnering initiatives with its lead clinical program.

Highlights:

- **Weight Gain:** Patients escalated to the 1300 microgram dose achieved a +6.38% mean weight gain after 12 weeks, compared to a -5.42% average loss on placebo. The maximum gain observed was +18.5% on ART27.13 versus only +0.4% on placebo.
- **Lean Body Mass:** At one month, patients treated with ART27.13 experienced a +4.23% increase in lean body mass, while placebo patients lost -3.15%.
- **Activity:** Patients receiving treatment showed improvements in activity scores and in moderate and vigorous activity, the latter being an endpoint that may be required by regulators for drug approval.
- **Safety:** ART27.13 was well tolerated. The most common adverse events were mild or moderate. No new safety signals were observed and interim safety results were consistent with Phase 1 of CAReS.

Barry Laird, Professor of Palliative Medicine, Oslo University Hospital - Radium Hospital and University of Oslo, Norway, and Chief Investigator in CAReS said, "The findings from the CAReS Phase 2 interim analysis build on the strong safety profile and signal from the Phase 1 trial and provide encouraging data supporting efficacy of ART27.13 on weight and physical activity in patients with advanced cancer."

The Phase 2 CAReS study is evaluating ART27.13 as a once-daily oral treatment aimed at improving weight, appetite, activity, and quality of life in cancer patients who had lost a minimum of 5% of their body weight in the prior six months. Effectiveness was measured by changes in lean body mass, weight, appetite, and activity over 12 weeks and at a 30-day follow-up. Activity and quality of life were assessed using wearable monitors and standardized questionnaires, while safety was closely tracked through adverse event reporting, laboratory tests, vital signs, visual analogue scales, and ECGs.

In the interim analysis, 18 evaluable patients—primarily with lung and gastrointestinal cancers not receiving cyclic chemotherapy—were included. After 12 weeks of treatment in patients who titrated to the top dose evaluated of 1300 micrograms (n=5), ART27.13 demonstrated compelling increases in mean body weight of 6.38% (Standard Deviation or SD 9.50) compared to patients on placebo (n=6) who lost -5.42% (SD 8.17). The maximum weight gain in the ART27.13 group reached 18.5%, versus only 0.4% in placebo. The maximum weight loss in the placebo arm was -17.4%, compared to just -3.0% in the ART27.13 group. Additional benefits were seen in lean body mass, with a +4.23% increase (SD 5.37) in the treatment group versus a -3.15% loss (SD 4.89) in placebo at one month, as well as qualitative improvements in total and weekly activity scores.

Safety results were consistent with prior findings. Among the 32 participants enrolled in the CAReS Phase 2 trial to date, 7 patients (22%) experienced adverse events that may be related to ART27.13. All were mild or moderate, with the exception of a single case of severe malaise, and no drug-related serious adverse events were reported. These data are aligned with safety outcomes observed in Phase 1 of CAReS, supporting ART27.13's overall favorable tolerability and acceptable safety profile.

"These data represent a reassuring and convincing drug effect for the highest dose of ART27.13 tested," stated Steven Reich, MD, Chief Medical Officer of Artelo. "For patients facing the devastating effects of cancer anorexia and cachexia, we believe these findings are particularly promising, especially for the Phase 2 protocol patients that had intra-patient dose-escalation. With these interim results, we are evaluating plans to advance the ART27.13 program by starting patients at the highest dose, which has the greatest treatment effect and acceptable safety."

Gregory D. Gorgas, President and CEO of Artelo, commented, "Based on the strength of this data and the recently announced Notice of Allowance for the patent application covering our intended commercial formulation through 2041, we are rapidly accelerating our licensing strategy as the most value-accretive path forward. We are in the process of sharing these results with global and regional pharmaceutical companies already familiar with ART27.13 who were awaiting this randomized data from the CAReS trial. Through this targeted effort we aim to speed development and maximize value for our shareholders."

About ART27.13

ART27.13 is a novel benzimidazole derivative being developed as a once-daily, orally

administered agent selectively targeting peripheral CB_1 and CB_2 receptors, with the potential to improve body weight, appetite, muscle degeneration, and quality of life in cancer patients. Initially developed by AstraZeneca plc, ART27.13 has been in seven clinical studies with over 280 participants. A statistically significant and dose-dependent increase in body weight was observed in people with back pain who were otherwise healthy. Importantly, the drug enables systemic metabolic effects while minimizing central nervous system-mediated toxicity. Having completed a Phase 1 study in cancer patients where ART27.13 demonstrated an excellent safety profile, Artelo is conducting a Phase 2 trial as a supportive care therapy for cancer patients suffering from anorexia and weight loss. Currently, there is no FDA approved treatment for cancer anorexia cachexia syndrome.

About CAReS

The Cancer Appetite Recovery Study (CAReS) is a Phase 1/2 randomized, placebo-controlled trial of the Company's lead clinical program, ART27.13, in patients with cancer anorexia and weight loss. Cancer-related anorexia, or the lack or loss of appetite in the person with cancer, may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for people with cancer to lose weight. Anorexia and the resulting weight loss can affect a patient's health, often weakening their immune system and causing discomfort and dehydration. A weight loss of more than 5% can predict a poor outcome for cancer patients and a lower response to chemotherapy. The Phase 1 portion of the CAReS study was designed to determine the most effective and safest initial dose of ART27.13 in the Phase 2 stage. The Phase 2 portion of the CAReS study is designed to determine estimates of activity of ART27.13 in terms of lean body mass, weight gain, and improvement of anorexia compared to placebo.
(ISRCTN registry: https://www.isrctn.com/ISRCTN15607817)

About CACS

Cancer Anorexia-Cachexia Syndrome (CACS) is a condition marked by loss of appetite, weight loss, and the breakdown of muscle and fat, affecting up to 80% of patients with advanced cancer- representing a greater than $3 billion addressable market. This loss of appetite, known as anorexia, may result from the cancer itself or from treatments such as radiation and chemotherapy. The resulting weight loss can weaken the immune system, cause discomfort and dehydration, and lower a patient's ability to tolerate treatment. Losing more than 5% of body weight is associated with poorer outcomes and reduced response to chemotherapy. While drugs that stimulate appetite have been used to help manage cancer-related anorexia, there are currently no approved treatments in the US, UK, or EU for this condition.

About Artelo Biosciences

Artelo Biosciences, Inc. is a clinical-stage pharmaceutical company dedicated to the development and commercialization of proprietary therapeutics that modulate lipid-signaling pathways, with a diversified pipeline addressing significant unmet needs in anorexia, cancer, anxiety, dermatologic conditions, pain, and inflammation. Complementing its scientific innovation, Artelo has adopted a forward-looking corporate finance initiative whereby it is deploying a portion of its excess capital into Solana under its digital asset treasury strategy. Led by an experienced executive team collaborating with world-class researchers and digital-asset technology partners, Artelo applies rigorous scientific, regulatory, commercial, and treasury management practices to maximize stakeholder value. More information is available at www.artelobio.com and X: @ArteloBio.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, including future plans in respect to ART27.13, potential transactions with pharmaceutical companies or other strategic counterparties in respect of ART27.13, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission, including our ability to raise additional capital in the future. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by applicable securities laws.

Investor Relations Contact:
Crescendo Communications, LLC
Tel: 212-671-1020
Email: ARTL@crescendo-ir.com

Source: Artelo Biosciences