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Artelo Biosciences Initiates the Phase 2a Portion of its CARES Trial Evaluating ART27.13 for the Treatment of Cancer-Related Anorexia and Weight Loss

SOLANA BEACH, Calif., April 25, 2023 (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, and neurological conditions, today announced it has initiated the Phase 2a portion of its Cancer Appetite Recovery Study (CAREs), evaluating ART27.13 for the treatment of cancer-related anorexia and weight loss.

“To date, ART27.13 has shown favorable tolerability in patients with anorexia and weight loss related to cancer with no significant negative effects attributed to the experimental drug,” said Steven D. Reich, M.D., Chief Medical Officer of Artelo. “Based on the positive safety profile and the response pattern observed in the Phase 1b portion of the trial, a dose of 650 micrograms will be administered to patients in the Phase 2a.”

The Phase 2a portion of the CAREs study is a double-blind, placebo-controlled design enrolling 40 patients randomly allocated in a 3:1 ratio to receive ART27.12 or placebo once daily for up to 12 weeks. The study is planned to be conducted at approximately 18 clinical sites in five countries.

“We believe ART27.13 can provide a novel way to manage the debilitating effects of anorexia and weight loss in cancer patients who have few, if any, alternatives,” said Gregory D. Gorgas, Artelo’s President and Chief Executive Officer. “By tripling the number of treatment centers and broadening patient eligibility criteria to include concurrent anti-cancer therapies, our goal is to complete Phase 2a patient enrollment by mid-2024.”

About ART27.13

ART27.13 is a highly potent, peripherally restricted synthetic, dual G-Protein-Coupled Receptor agonist believed to target the cannabinoid receptors CB₁ and CB₂, which has the potential to increase appetite and food intake. Originally developed by AstraZeneca plc, ART27.13 has been evaluated in five Phase 1 clinical studies including over 200 subjects where it has demonstrated a statistically significant and dose-dependent increase in body weight in healthy subjects. Importantly, the changes in body weight were not associated with fluid retention and the distribution of the drug enables systemic metabolic effects while minimizing central nervous system-mediated toxicity. Artelo is advancing ART27.13 as a supportive care therapy for cancer patients suffering from anorexia and weight loss, where the current annual global market is estimated to be valued in excess of \$2 billion.

About CAREs

The Cancer Appetite Recovery Study (CAREs) is a Phase 1b/2a randomized, placebo-controlled trial of the Company's lead clinical program, ART27.13, in patients with cancer anorexia and weight loss. Anorexia, or the lack or loss of appetite, may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for patients 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 1b portion of the CAREs study is designed to determine the most effective and safest dose of ART27.13 for dosing in the Phase 2a stage. The Phase 2a 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. (ISRCTN registry: <https://www.isrctn.com/ISRCTN15607817>)

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 including the endocannabinoid system. Artelo is advancing a portfolio of broadly applicable product candidates designed to address significant unmet needs in multiple diseases and conditions, including anorexia, cancer, anxiety, pain, neuropathy, and inflammation. Led by proven biopharmaceutical executives collaborating with highly respected researchers and technology experts, the company applies leading edge scientific, regulatory, and commercial discipline to develop high-impact therapies. More information is available at www.artelobio.com and Twitter: [@ArteloBio](https://twitter.com/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, 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



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