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Artelo Biosciences Completes Enrollment of the First Three Cohorts in its CAReS Study Evaluating ART27.13 for the Treatment of Cancer-Related Anorexia and Weight Loss

Initiates Fourth Cohort at a 650-Microgram Dose with Data Expected in Q4 2022

SOLANA BEACH, Calif., July 19, 2022 (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 the completion of enrollment of the first three cohorts in the Cancer Appetite Recovery Study (CAReS) and the initiation of a fourth cohort expected to complete the first stage of the Phase 1b clinical trial of ART27.13.

“The CAReS safety review committee has reviewed the data thus far and has concluded that ART27.13 has been well-tolerated with no serious adverse events attributable to the investigational drug in patients suffering from anorexia associated with cancer,” said Steven D. Reich, M.D., Chief Medical Officer of Artelo. “Remarkably, the safety profile of ART27.13 appears more benign among cancer patients participating in CAReS than observed in healthy volunteers in prior Phase 1 studies. Furthermore, we have seen pharmacokinetics consistent with the AstraZeneca experience and an improvement in anorexia from each dose escalation.”

The CAReS Phase 1b stage focuses on the safety of ascending doses with the objective of identifying the optimal dose for the randomized Phase 2a portion of the study, in which additional safety and activity will be evaluated. The mild to moderate adverse events observed in CAReS that have been attributed to ART27.13 required no dose reductions or terminations and many of the adverse events required no medical intervention at all. Given the encouraging safety profile and dose-response trend to date, with the goal of maximizing potential utility of ART27.13, Artelo has elected to open enrollment for six patients at a 650 microgram dose per the option in the approved study protocol.

“We remain highly encouraged by the clinical observations among the patients successfully enrolled in CAReS,” added Gregory D. Gorgas, President and Chief Executive Officer of Artelo. “With six participating sites in three countries, we expect to efficiently complete the Phase 1b stage of CAReS during the third quarter and initiate the randomized Phase 2a in the fourth quarter of this year, which is planned to include additional sites in Europe and the

United Kingdom."

About ART27.13
ART27.13 is a highly potent, peripherally restricted synthetic, dual G-Protein Couple Receptor agonist believed to target the cannabinoid receptors CB_1 and CB_2, which has the potential to increase appetite and food intake. Originally developed by AstraZeneca plc, ART27.13 has been in five Phase 1 clinical studies including over 200 subjects where it 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 in cancer patients, 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.

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.

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