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Artelo Biosciences Doses First Patient in CARES Study with ART27.13 for the Treatment of Cancer-Related Anorexia and Weight Loss

Initial safety data expected from CARES Study before end of 2021

Targeting multi-billion market with no approved therapies for cancer-related anorexia

LA JOLLA, Calif., April 12, 2021 (GLOBE NEWSWIRE) -- [Artelo Biosciences, Inc.](#) (**NASDAQ: ARTL**), a clinical stage biopharmaceutical company focused on the development of therapeutics that target lipid-signaling pathways, including the endocannabinoid system, today announced that the first patient has been dosed in the Company's Phase 1/2 Cancer Appetite Recovery Study (CAREs) of ART27.13 in Edinburgh, Scotland, UK. ART27.13 is a peripherally selective G-Protein Coupled Receptor (GPCR) full agonist that is being developed as a much-needed therapy for cancer patients suffering from anorexia and weight loss, which affects over 60% of later-stage cancer patients, often impacts quality of life, and can hasten death.

"Commencing enrollment and dosing the first patient in our CAREs study marks another important milestone in advancing ART27.13, which we are developing for patients suffering from the devastating effects of cancer associated anorexia—a multi-billion-dollar addressable market with no pharmacologic standard of care," stated Andrew Yates, Ph.D., Senior Vice President and Chief Scientific Officer of Artelo. "Notably, we anticipate that we will be able to collect initial safety data from Phase 1 of CAREs before the end of this year, which will determine the most effective and safest dose of ART27.13 to utilize in Phase 2 of the study. ART27.13 has previously demonstrated weight gain in subjects with lower back pain and we look forward to conducting the study in anorexic cancer patients who have suffered significant weight loss."

"This is an exciting time for a clinical study with Artelo's lead development drug. So many patients have suffered with substandard options to address the profound weight loss from cancer. With ART27.13 there are grounds for optimism that loss of appetite associated with cancer can be successfully treated," added the lead investigator Barry J.A. Laird, M.D., from the Institute of Genetics and Cancer at the University of Edinburgh, Scotland and enrolling physician of the first participating patient.

About ART27.13

ART27.13 is a highly potent, peripherally restricted synthetic, dual GPCR agonist believed to target the cannabinoid receptors CB₁/CB₂, 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 1/2 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 1 portion of the CAREs study is designed to determine the most effective and safest dose of ART27.13 that will be used in the Phase 2 stage. The Phase 2 portion of the CAREs study is designed to determine point estimates of activity of ART27.13 in terms of lean body mass, weight gain, and improvement of anorexia. The study is planned to enroll up to 24 patients in the Phase 1 and 25 participants in the Phase 2.

(ISRCTN registry: <https://www.isrctn.com/ISRCTN15607817>)

About Artelo Biosciences

Artelo Biosciences, Inc. is a San Diego-based biopharmaceutical company dedicated to the development and commercialization of proprietary therapeutics targeting endogenous signaling pathways including the endocannabinoid system. Artelo is rapidly advancing a portfolio of broadly applicable product candidates designed to address significant unmet needs in multiple diseases and conditions, including anorexia, cancer, PTSD, pain, 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.

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