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Artelo Biosciences Announces Clinical Trial Authorization to Commence Cancer Appetite Recovery Study for the Treatment of Cancer-Related Anorexia and Weight Loss

First patients on track for enrollment this year

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

LA JOLLA, Calif., Nov. 16, 2020 (GLOBE NEWSWIRE) -- Artelo Biosciences, Inc. (NASDAQ: ARTL), a clinical stage biopharmaceutical company focused on the development of therapeutics that modulate endogenous signaling pathways, including the endocannabinoid system, today announced receipt of the Clinical Trial Authorization (CTA) in the UK for the Company's Cancer Appetite Recovery Study (CAReS). The Medicines and Healthcare products Regulatory Agency (MHRA) authorized the initiation of the study entitled "A Phase 1/2 Trial of Synthetic Cannabinoid ART27.13 in Patients with Cancer Anorexia and Weight Loss." Artelo expects the study to initiate enrollment before year end.

"Receiving our Clinical Trial Authorization clears the path to commence our CAReS trial and we are excited about the prospect of enrolling patients this year," stated Andrew Yates, PhD., Program Leader for ART27.13. "We will now proceed to open up sites throughout the UK with an overall recruitment goal of 43 patients, while maintaining safe and efficient operations during the Covid-19 pandemic."

Steven D. Reich, M.D., Artelo's Chief Medical Officer, added, "Cancer-related anorexia is a dramatically underserved market, with no approved therapies." Cancer-related anorexia affects greater than 60% of advanced stage cancer patients and it is characterized by loss of appetite, weight loss, poor quality of life and often precedes a patient's death. Reich continued, "The Phase 1/2 CAReS trial is designed to determine the most effective and safest dose and to evaluate activity using criteria such as lean body mass, weight gain, and improvement of anorexia."

About Artelo Biosciences

Artelo Biosciences, Inc. is a San Diego-based biopharmaceutical company dedicated to the development and commercialization of proprietary therapeutics that modulate 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, pain, inflammation,

and anxiety. 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.

About ART27.13

ART27.13 is a highly potent, peripherally restricted synthetic, dual G protein-coupled receptor agonist believed to target peripheral CB_1/CB_2 receptors, 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 plans to advance 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.

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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