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Artelo Biosciences Receives Ethics Approval to Commence its Cancer Appetite Recovery Phase I/II Clinical Study (CAReS) of ART27.13 for the Treatment of Cancer-Related Anorexia

Barry J. A. Laird, M.D. of the University of Edinburgh's Institute of Genetics and Molecular Medicine Appointed Coordinating Investigator

LA JOLLA, Calif., Sept. 29, 2020 (GLOBE NEWSWIRE) -- **Artelo Biosciences, Inc.** (**NASDAQ: ARTL**), a clinical stage biopharmaceutical company focused on the development of therapeutics that modulate the endocannabinoid system, today announced the receipt of Ethics Committee approval in the U.K. for the Company's Cancer Appetite Recovery Study (CAReS) entitled A Phase 1/2 Trial of the Synthetic Cannabinoid [ART27.13](#) in Patients with Cancer Anorexia and Weight Loss. [Barry J. A. Laird, M.D.](#) of the Institute of Genetics and Molecular Medicine at the University of Edinburgh and St. Columbia's Hospice Reader in Palliative Medicine, will serve as the coordinating investigator. ART27.13 is a highly potent, peripherally restricted synthetic, dual cannabinoid agonist believed to target peripheral CB₁/CB₂ receptors, and has the potential to increase appetite and food intake. Artelo intends to initially develop ART27.13 as a supportive care therapy for cancer patients suffering from anorexia and weight loss.

"Receiving Ethics Committee approval is an essential step towards commencing our CAReS trial in the UK," stated Steven D. Reich, M.D., Artelo's Chief Medical Officer. "We are very pleased to have Dr. Laird as our Coordinating Investigator as we believe that his extensive knowledge of and focus on palliative medicine as well as his direct expertise in clinical trials evaluating treatments for anorexia will be invaluable as we evaluate ART27.13. We are working diligently on securing the additional regulatory requisite approvals which will enable us to open our clinical sites and initiate patient enrollment later this year."

"As an academic clinician, I am passionate about improving symptoms in people with life-limiting illness and I am honored to be working with Artelo on this exciting program and the CAReS clinical trial," stated Dr. Laird. "My team's overarching goal is to help find therapies which improve the care of patients with cancer and I look forward to evaluating the potential of ART27.13 to reduce the devastating symptoms and improve quality of life of those suffering from this disease."

About the CAReS Study

CAReS is a Phase 1/2 clinical trial of the synthetic cannabinoid ART27.13 in patients with

cancer anorexia and weight loss, which will enroll up to 49 subjects, initially in clinical trial sites located in the U.K. The primary endpoint in Phase 1 of the study is to determine the most effective and safe dose of ART27.13 to be utilized in Phase 2. The primary endpoint in Phase 2 of the study is to determine point estimates of activity of ART27.13 in terms of lean body mass, weight gain, and improvement of anorexia.

About ART27.13

ART27.13 is a potent, peripherally restricted dual synthetic agonist of the CB₁/CB₂ receptors. Existing ART27.13 clinical data suggests meaningful potential for the treatment of cancer-related anorexia and weight loss. In five Phase I clinical studies including over 200 subjects, ART27.13 previously demonstrated a statistically significant and dose-dependent increase in body weight in subjects without cancer. Artelo plans to advance ART27.13 as a supportive care therapy for cancer patients suffering from anorexia and weight loss.

About Artelo Biosciences, Inc.

Artelo Biosciences, Inc. is a San Diego-based biopharmaceutical company dedicated to the development and commercialization of proprietary therapeutics targeting 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, post-traumatic stress disorder, pain, and inflammation. Led by proven biopharmaceutical executives collaborating with highly respected researchers and medical 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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