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# Artelo Anticipates Accelerated Clinical Development for ART27.13 Following Its Classification Change in the United Kingdom

SOLANA BEACH, Calif., Jan. 11, 2022 (GLOBE NEWSWIRE) -- [Artelo Biosciences, Inc.](#) (Nasdaq: ARTL) announced that the United Kingdom's Home Office has classified the Company's lead clinical cannabinoid, [ART27.13](#), as "non-controlled" and, therefore, is no longer considered a Schedule 1 controlled substance, which would impose limitations on its production, possession, and supply. The Home Office is the lead government department tasked with major economic, security and safety policies, including drug policy.

"Collaborating diligently with the Home Office, Artelo was successful in working with governmental regulators to determine that the chemical composition of ART27.13 should not be covered by the Misuse of Drugs Act and, by virtue of the ongoing clinical trials, was also exempted from the Psychoactive Substances Act in the U.K.," stated Andrew Yates, Ph.D., Chief Scientific Officer of Artelo Biosciences. "As a result, Artelo will be able to treat ART27.13 as a normal, non-scheduled Investigational Medicinal Product, which is expected to streamline onboarding of additional clinical sites in the U.K., accelerate enrollment of patients, and enhance the commercial potential of ART27.13," added Dr. Yates.

Artelo is currently enrolling patients in the U.K. in a Phase 1/2 Cancer Appetite Recovery Study (CAREs) to evaluate ART27.13 for the treatment of anorexia in people with cancer. Cancer anorexia affects up to 60% of patients with advanced-stage cancers and is characterized by loss of appetite, weight loss and tissue wasting, impoverishing quality of life, and often precedes a patient's death. ART27.13 was designed to be peripherally restricted, targeting the cannabinoid receptors in the body's periphery and not the brain, which is a distinguishing feature of the synthetic cannabinoid. Avoiding receptors in the central nervous system (CNS) has the potential to deliver an effective dose for managing anorexia while minimizing any undesired CNS effects.

## About ART27.13

ART27.13 is a highly potent, peripherally restricted synthetic, dual GPCR agonist believed to target the cannabinoid receptors CB<sub>1</sub>/CB<sub>2</sub>, 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 the CARES Study**

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: the <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 target 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, PTSD, pain, and inflammation. Led by proven pharmaceutical executives collaborating with highly respected researchers and technology experts, Artelo applies leading edge scientific, regulatory, and commercial discipline to develop high-impact therapies. More information is available at [www.artelobio.com](http://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 Artelo'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 Artelo'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. Artelo 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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