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Artelo Biosciences Announces Selection of Aptus Clinical Ltd. as Clinical Research Organization for Phase 1b/2a Study of ART27.13

LA JOLLA, Calif., Oct. 29, 2019 (GLOBE NEWSWIRE) -- [Artelo Biosciences, Inc. \(NASDAQ: ARTL\)](#), a clinical stage biopharmaceutical company developing therapeutics that modulate the endocannabinoid system, announced today that it has selected [Aptus Clinical Ltd.](#) (Aptus), a specialist Clinical Contract Research Organization based in the United Kingdom (UK) with particular expertise in oncology, rare diseases and advanced therapies, as its contract research organization (CRO) for the Company's planned Phase 1b/2a randomized, placebo-controlled trial of [ART27.13](#), its synthetic cannabinoid for the treatment of anorexia and weight loss associated with cancer. This latest agreement builds on earlier collaborations between Artelo and Aptus, which included feasibility studies, protocol design, and clinical site identification and selection. The ART27.13 program will continue to be under the operational stewardship of Artelo's UK subsidiary at the Alderley Park BioHub in Cheshire.

ART27.13 is a highly potent peripherally selective synthetic dual cannabinoid agonist believed to target peripheral cannabinoid receptors sending a feeding message to the brain. The combined Phase 1b/2a trial is expected to enroll up to 49 subjects at clinical sites within the UK. The study is designed to determine the most effective and well tolerated dose in cancer patients and evaluate activity using criteria such as weight gain, lean body mass, and improvement of anorexia.

Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences, commented, "We are excited to expand our relationship with Aptus, which will allow us to leverage their broad experience as well as their understanding of local regulatory processes combined with a wide network of investigators and key opinion leaders. We look forward to providing further updates as we commence our Phase 1b/2a trial and advance our cancer anorexia program."

Steve McConchie, Chief Executive Officer of Aptus Clinical, added, "We are honored to have been selected by Artelo to help oversee this important trial. Despite the fact that cancer-related anorexia affects about 60% of advanced stage cancer patients, there are no FDA approved drugs for this indication and only a few agents used off-label with limited efficacy. Clearly, patients deserve better and the profile of Artelo's product candidate is compelling."

About ART27.13

ART27.13 is a potent, peripherally selective CB₁/CB₂ synthetic agonist that enables

systemic metabolic effects, while minimizing central nervous system mediated side effects. ART27.13 has been previously evaluated in 205 subjects across five Phase 1 studies conducted by AstraZeneca plc. Existing clinical data with ART27.13 suggests meaningful potential for the treatment of cancer-related anorexia and weight loss as ART27.13 demonstrated a statistically significant and dose-proportional increase in body weight. In ongoing consultation with regulatory authorities, Artelo plans to advance ART27.13 as a multi-modal supportive care therapy for cancer patients suffering from anorexia or weight loss.

About Artelo Biosciences, Inc.

Artelo Biosciences, Inc. is a San Diego-based biopharmaceutical company, with fully owned subsidiaries in the UK and Ireland, 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, 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).

About Aptus Clinical Ltd.

Aptus Clinical Limited is a clinical contract research organization that specializes in the design, conduct and delivery of early phase clinical studies with a particular focus in oncology, rare diseases, cell and gene therapies. Projects are delivered by a team of highly experienced drug development experts utilizing their extensive network of academic links. Aptus aims to partner with clients to help them transform their promising molecules into valued medicines. For more information, visit www.aptusclinical.com and Twitter: [@aptusclinical](https://twitter.com/aptusclinical).

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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