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Artelo Biosciences Announces Selection of Worldwide Clinical Trials as Clinical Research Organization to Support First-in-Human Study of ART26.12

SOLANA BEACH, Calif., Jan. 08, 2024 (GLOBE NEWSWIRE) -- Artelo Biosciences, Inc. **(Nasdaq: ARTL),** a clinical-stage pharmaceutical company focused on modulating lipid-signaling pathways to develop treatments for people living with cancer, pain, and neurological conditions, today announced that it has selected Worldwide Clinical Trials ("Worldwide"), a global award-winning contract research organization (CRO) therapeutically focused on neuroscience, oncology, rare diseases, and cardiometabolic and inflammatory disease, to support the Company's planned Phase 1 trial with ART26.12, its Fatty Acid Binding Protein 5 (FABP5) inhibitor in development for the treatment of chemotherapy-induced peripheral neuropathy (CIPN).

"We look forward to working with Worldwide once we obtain approval from the FDA to advance ART16.12 into Phase 1 clinical development," commented Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "With Worldwide's extensive experience in the neurology space and successful track record of assisting companies progress through trials, we believe we are well positioned to leverage ART26.12's positive profile observed in multiple animal models of painful neuropathies to progress to human studies."

"We are excited to partner with the Artelo Biosciences team on their important advancement with ART26.12," stated Peter Benton, President and Chief Executive Officer of Worldwide Clinical Trials. "Given the broad potential of lipid-signaling in therapeutics development and more specifically the prospects for ART26.12 as a non-opioid pain drug, we look forward to supporting Artelo in the evaluation of safety with their promising FABP5 inhibitor."

According to Coherent Market Insights, the global neuropathic pain market is estimated to be valued at $7.6 billion, demonstrating the need for an innovative therapy that has the potential to provide relief for pain patients with few treatment options. Artelo has conducted five pre-clinical studies in painful neuropathies, including diabetic neuropathy and chemotherapy-induced peripheral neuropathy, the latter of which has no FDA-approved treatment. The Company previously reported a positive pre-IND (investigational new drug) meeting with the Food and Drug Administration and anticipates filing the IND for ART26.12 in the first half of this year.

About ART26.12
Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone

lipids including endocannabinoids and fatty acids. FABP is overexpressed and associated with abnormal lipid signaling in a number of pathologies. ART26.12, Artelo's lead FABP inhibitor, is a potent and selective inhibitor of FABP5 being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic, with an initial clinical study planned for chemotherapy-induced peripheral neuropathy (CIPN). Beyond ART26.12, Artelo's extensive library of small molecule inhibitors of FABPs have shown therapeutic promise for the treatment of certain cancers, neuropathic and nociceptive pain, and anxiety disorders.

About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality. Worldwide's capabilities include bioanalytical laboratory services, Phase I-IV clinical trials, and post-approval and real-world evidence studies – all powered by an accessible team of clinicians, scientists, and researchers who bring first-hand expertise and a collaborative, personalized approach to each clinical program. Worldwide is therapeutically focused on neuroscience, oncology, rare diseases, and cardiometabolic and inflammatory disease. Its global footprint spans nearly 60 countries with more than 3,400 team members. For more information, visit www.worldwide.com.

About Artelo Biosciences

Artelo Biosciences, Inc. is a clinical stage pharmaceutical company dedicated to the development and commercialization of proprietary therapeutics that modulate 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, anxiety, 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.

About CIPN

Chemotherapy induced peripheral neuropathy (CIPN) is a type of neuropathic pain caused by chemotherapy as well as non-chemotherapy cancer treatments such as immunomodulating drugs. CIPN is a major challenge with many oncological treatments, sometimes resulting in dose reduction or cessation of the cancer treatment, negatively impacting efficacy and survival. Acute CIPN occurs during chemotherapy and chronic CIPN can last months to years. Around 30% of patients will still have CIPN a year, or more, after finishing chemotherapy.

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.

Investor Relations Contact:
Crescendo Communications, LLC
Tel: 212-671-1020
Email: ARTL@crescendo-ir.com

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