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Artelo Biosciences Announces Successful Completion of First Cohort in a Phase 1 Study of ART26.12

The first selective Fatty Acid Binding Protein 5 inhibitor safely administered to human subjects

Initial safety and pharmacokinetic data expected during the first half 2025

SOLANA BEACH, Calif., Jan. 13, 2025 (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, or dermatologic and neurological conditions, today announced the completed safety review of the first cohort of eight healthy volunteers in the Company's Phase 1 study of ART26.12. Progression to the next cohort marks a major milestone in the development of Fatty Acid Binding Protein (FABP) inhibitors as a novel treatment approach for a large number of potential indications.

ART26.12 is the lead compound in Artelo's proprietary FABP platform and is believed to be the first-ever selective FABP5 inhibitor to enter clinical trials. The FABP5 target is an intracellular protein involved in lipid signalling, heralding a promising mechanism of action for modifying the cellular lipidome. In development as a non-opioid approach to the management of painful neuropathies, ART26.12 has already demonstrated significant promise in multiple preclinical pain models including, Chemotherapy Induced Peripheral Neuropathy (CIPN), Diabetic Neuropathy, cancer bone pain and osteoarthritis.

"We are pleased to report on the progress with ART26.12, our lead FABP inhibitor," said Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "Based on the encouraging safety profile of ART26.12 in preclinical studies, we look forward to learning from the initial safety, pharmacokinetic, and biomarker data from this ongoing human study, which is expected to be completed during the first half of 2025. As the leading company pursuing FABP inhibition, we are committed to building on the unique, lipid-modulating mechanism of FABP inhibition to address the unmet needs of patients reliant on medicines that are often ineffective and intolerable. ART26.12 is the first clinical stage candidate drug from our extensive FABP inhibitor platform."

With dosing already underway, the next cohort in the Phase 1 study will provide additional insight into the development of this unprecedented approach to harnessing the power of FABP inhibition. Results from the current Phase 1 single ascending dose study are intended to determine the most suitable doses of ART26.12 to utilize in a multiple ascending dose study evaluating ART26.12 in healthy volunteers planned for the second half of 2025.

About ART26.12

ART26.12, Artelo's lead Fatty Acid Binding Protein 5 (FABP5) inhibitor, is a potent and selective inhibitor of FABP5 being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic, with initial clinical development planned for chemotherapy-induced peripheral neuropathy (CIPN). ART26.12 is currently in a Phase 1 study being conducted by Worldwide Clinical Trials at their Clinical Pharmacology Unit in San Antonio, Texas, USA. Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone lipids important to normal cellular function. FABP is overexpressed and associated with abnormal lipid signaling in a number of pathologies. Invented by Distinguished Professor Iwao Ojima working in collaboration with Professor Martin Kaczocha, both at Stony Brook University, the extensive library of FABP inhibitors was exclusively licensed to Artelo with global rights. Beyond ART26.12 in CIPN, Artelo's FABPs have shown therapeutic promise for the treatment of certain cancers, neuropathic and nociceptive pain, psoriasis, and anxiety disorders.

About CIPN

CIPN is a type of neuropathic pain caused by chemotherapy. Some chemotherapies result in CIPN with 90% frequency. CIPN often results in dose reduction or cessation of the cancer treatment leading to negative impacts on efficacy and survival. Acute CIPN occurs during chemotherapy treatment while chronic CIPN can last months to years. No FDA-approved treatment currently exists for CIPN. A new treatment or preventative intervention for CIPN holds promise to not only address debilitating pain, but also serve as an enabler of essential anti-cancer therapy. A new proprietary treatment for CIPN is anticipated to be a multi-billion-dollar market opportunity.

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. 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, dermatologic conditions, 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.

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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