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Artelo Biosciences Receives FDA Clearance of its IND Application for ART26.12, a Selective Fatty Acid Binding Protein 5 Inhibitor

ART26.12 seeks to address a critical need in painful neuropathies, including chemotherapy-induced peripheral neuropathy for which there is no FDA-approved treatment

Phase 1 trial results expected in the first half of 2025

SOLANA BEACH, Calif., July 15, 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, dermatologic and neurological conditions, today announced that the U.S. Food and Drug Administration (FDA) has issued a “Study May Proceed” letter for the Company’s Investigational New Drug (IND) application for ART26.12, for the treatment of chemotherapy-induced peripheral neuropathy (CIPN). FDA clearance of the ART26.12 IND application enables the Company to initiate its first-in-human Phase 1 single ascending dose study. Study startup activities have been initiated in collaboration with the internationally known contract research organization Worldwide Clinical Trials.

ART26.12 is the lead compound in the Company’s proprietary Fatty Acid Binding Protein (FABP) platform and the first selective FABP5 inhibitor to enter clinical trials. The FABP5 target is an intracellular protein involved in lipid signaling and represents a promising mechanism of action for drug candidates that can modify the cellular lipidome. ART26.12 is being developed as a non-opioid approach to the management of painful neuropathies. The Company’s FABP inhibitor platform, and ART26.12 in particular, has garnered interest from a range of potential partners due to its preclinical demonstation of efficacy, novel mechanism, and strong patent estate.

“Receiving IND clearance validates our development efforts and underscores the potential impact of ART26.12 to improve patients’ lives,” said Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. “We look forward to sharing the initial clinical results with ART26.12 next year. As the leading company pursuing FABP inhibiton we are committed to building on the unique, lipid-modulating mechanism of our FABP inhibitor platform to address life-altering pathologies for which there are few, if any, safe and effective pharmaceutical treatments.”

About ART26.12

Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone

lipids involved in cellular signaling. FABPs are often overexpressed and associated with abnormal lipid signaling in a number of pathologies. ART26.12, Artelo's lead FABP inhibitor program in clinical development, is a potent and selective small molecule inhibitor of FABP5 being developed as an orally delivered, peripherally acting, non-opioid, new chemical entity for cancer patients suffering from chemotherapy- induced peripheral neuropathy. 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. Preclinical evidence to date suggest FABP inhibition has broad therapeutic promise for the treatment of multiple cancers, painful neuropathies, cancer bone pain, dermatologic conditions and anxiety disorders.

About CIPN

Chemotherapy-induced peripheral neuropathy (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.

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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