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# Artelo Biosciences Announces Positive First-in-Human Data for ART26.12, a Novel Non-Opioid Treatment Candidate for Persistent Pain

*First Orally Active Fatty Acid Binding Protein 5 Inhibitor Evaluated in Humans*

*First-in-Class Approach Targets Unmet Need in Multibillion-Dollar Pain Management Market*

SOLANA BEACH, Calif., June 30, 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, dermatological or neurological conditions, today announced favorable results from its first-in-human study evaluating ART26.12, a novel inhibitor of Fatty Acid Binding Protein 5 (FABP5). The results affirm the promising safety and pharmacokinetic (PK) profile previously observed in preclinical studies.

Inhibiting FABP5 represents a unique mechanism of action with ART26.12 standing out as a first-in-class candidate in the field of pain management. The Phase 1 Single Ascending Dose (SAD) study was designed to assess the safety, tolerability, and pharmacokinetics of ART26.12 in healthy volunteers. The SAD study enrolled 49 subjects.

**The key findings include:**

- **Excellent Safety Results**: All adverse events (AEs) were mild, transient, and self-resolving. No drug-related AEs were observed in the blinded dataset, and no tolerability issues or safety signals were detected across multiple assessments (vital signs, ECGs, clinical laboratory tests, physical examinations, and visual analogue mood scales).

- **Predictable PK**: Full dose-exposure profiles were successfully explored. Plasma analysis confirmed dose-dependent, linear absorption across the evaluated range.

- **Therapeutic Window**: A wide safety margin was observed between estimated therapeutic plasma concentrations and the highest exposure levels achieved, supporting potential titration for maximum efficacy in future studies.

Andrew Yates, Ph.D., Senior Vice President and Chief Scientific Officer at Artelo, commented, “We are greatly encouraged with the results of the SAD study with our lead FABP5 inhibitor and we are particularly pleased to observe that the safety and PK profile

that had been generated from ART26.12's non-clinical studies translated well to the human experience."

ART26.12 is the first orally administered, selective, and peripherally restricted FABP5 inhibitor to enter human clinical evaluation. By targeting FABP5, ART26.12 modulates endogenous lipid signaling molecules that exert analgesic effects through established pathways, including TRPV1, PPAR alpha, and cannabinoid receptors, with additional mechanisms such as Nav1.8 under investigation.

The chronic pain therapeutics market exceeded $97 billion globally in 2023 and is expected to surpass $159 billion by 2030[1], driven by the increasing prevalence of conditions such as neuropathic pain, arthritis, and fibromyalgia. Despite the scale of the market, innovation remains sparse—particularly for non-opioid therapies. As part of the U.S Food and Drug Administration's Overdose Prevention Framework, the Agency has issued draft guidance aimed at encouraging the development of non-opioid analgesics for pain. ART26.12 is positioned to fill this gap with an innovative mechanism of action and favorable safety profile. A Multiple Ascending Dose study to further evaluate the safety, tolerability, and pharmacokinetics of ART26.12 with repeated dosing over time is expected to commence in the fourth quarter this year.

**About ART26.12**

ART26.12, Artelo's lead FABP5 inhibitor, is being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic. The initial clinical development planned is for chemotherapy-induced peripheral neuropathy (CIPN). 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 several pathologies. In addition to ART26.12 in CIPN, Artelo's extensive library of small molecule inhibitors of FABPs has shown therapeutic promise for the treatment of certain cancers, neuropathic and nociceptive pain, anxiety disorders, and psoriasis. ART26.12 has been included in Helping to End Addiction Long-term® (HEAL) Initiative's Preclinical Screening Platform for Pain program of the U.S. National Institutes of Health. The HEAL program is dedicated to advancing non-opioid solutions to pain and curbing opioid use disorder.

[1] https://www.psmarketresearch.com/market-analysis/chronic-pain-treatment-market

**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 X: @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 future investment policy of its excess capital, 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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