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Artelo Biosciences Announces New Data from an Initial Food Effect Investigation with ART26.12, a Novel Non-Opioid Treatment Candidate for Persistent Pain

Safety and Pharmacokinetic Data Support Dosing of ART26.12 in Fed or Fasted Conditions

Completion of Positive Single Ascending Dose Study with a Preliminary Food Effect Assessment
Advances ART26.12 Toward Multiple Ascending Dose Trial

SOLANA BEACH, Calif., Aug. 25, 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 encouraging results from its preliminary food effect evaluation with ART26.12. This assessment was conducted as a part of the successful single ascending dose (SAD) Phase 1 clinical trial evaluating ART26.12, the first selective oral small molecule fatty acid binding protein 5 (FABP5) inhibitor dosed in the clinic.

The food effect interrogation was designed to assess the pharmacokinetics and safety profile ART26.12 in healthy volunteers under both fed and fasted conditions. The selected dose was based on previously established safety and pharmacokinetic data from the SAD study, where there were no drug-related adverse events reported.

Key findings include:

- **Favorable Safety Profile**: Participants received three single doses of ART26.12 separated by 7-day intervals. No serious adverse events, safety concerns, or tolerability issues were identified. All reported adverse events were mild, self-limiting, and consistent with those observed in the SAD study.
- **Predictable Pharmacokinetics**: Data showed consistent exposure levels under fasted conditions across the both the food effect evaluation and SAD study, indicating low inter-subject variability. Plasma pharmacokinetics further suggest ART26.12 can be effectively administered with or without food.
- **Clinical Development Momentum**: The profile observed from the SAD and Food Effect study provides a strong foundation for advancing to the upcoming multiple ascending dose (MAD) study.

“We are delighted to have successfully concluded our initial step in the human investigation

of ART26.12. The SAD and Food Effect study provides us with the knowledge that we can choose to dose in both the fed or fasted state in future trials," said Andrew Yates, Ph.D., Senior Vice President and Chief Scientific Officer at Artelo. "The results generated to date provide our first indication of predictable pharmacokinetic behavior and a benign safety profile—both of which are highly desirable in a pain drug intended for chronic use," continued Dr. Yates.

Preparations are underway to initiate a MAD study to further evaluate the safety, tolerability, and pharmacokinetics of ART26.12 with repeated dosing over time. The MAD study is planned to commence dosing subjects in the fourth quarter this year.

About ART26.12

ART26.12 is a selective, orally administered, and peripherally acting FABP5 inhibitor. ART26.12 represents a new therapeutic class with a non-opioid, non-steroidal analgesic approach designed to target a novel mechanism in pain modulation by altering endogenous lipid species in pain-relevant tissues. These lipid messengers influence multiple known pain pathways, including transient receptor potential vanilloid 1 (TRPV1), peroxisome proliferator-activated receptor alpha (PPAR-α), and cannabinoid receptors, with emerging evidence of modulation of additional targets such as Nav1.8. 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 and proprietary library of small molecule inhibitors of FABPs has shown therapeutic promise for the treatment of certain cancers, neuropathic and nociceptive pain, psoriasis, and anxiety disorders. The U.S. National Institutes of Health (NIH) has included ART26.12 in its Helping to End Addiction Long-term® (HEAL) initiative's Preclinical Screening Platform for Pain (PSPP) program. Through the HEAL PSPP, the NIH is dedicated to advancing non-opioid solutions to pain and curbing opioid use disorder.

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, with a diversified pipeline addressing significant unmet needs in anorexia, cancer, anxiety, dermatologic conditions, pain, and inflammation. Complementing its scientific innovation, Artelo adopted a forward-looking corporate finance initiative whereby it is deploying a portion of its excess capital into Solana under a digital asset treasury strategy. Artelo intends to leverage Solana to diversify its balance sheet, enhance liquidity management, and position the Company for long-term value creation to support its therapeutic programs. Led by an experienced executive team collaborating with world-class researchers and digital-asset technology partners, Artelo applies rigorous scientific, regulatory, commercial, and treasury management practices to maximize stakeholder value. 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 product development, timing of the Company's planned clinical trials and related data readouts, efficacy of the Company's product candidates, results and conclusions from preclinical studies and clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements 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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