September 10, 2025

Artelo Biosciences Announces Publication of Preclinical Data Demonstrating Superior Efficacy and Bioavailability of ART12.11 in Reducing Stress-Induced Depression and Anxiety Symptoms

SOLANA BEACH, Calif., Sept. 10, 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, dermatologic, or neurological conditions, today announced the publication of new preclinical data on ART12.11, its proprietary cannabidiol:tetramethylpyrazine (CBD:TMP) cocrystal.

The peer-reviewed study, conducted in collaboration with researchers at Western Ontario University, was published in *Progress in Neuro-Psychopharmacology and Biological Psychiatry* and highlighted that ART12.11 significantly outperformed cannabidiol (CBD) alone in reducing stress-induced depression and anxiety symptoms, while also achieving superior oral bioavailability.

Key Findings

- **Enhanced Efficacy:** ART12.11 reversed stress-induced behavioral deficits and produced robust anti-depressant and anxiolytic-like effects. These benefits were superior to CBD alone, TMP alone, or a non-crystalline mixture of CBD and TMP.
- **Improved Bioavailability:** Oral administration of ART12.11 resulted in higher plasma concentrations of CBD and its major metabolite, highlighting improved pharmacokinetic properties over conventional CBD formulations.
- **Mechanistic Insights:** ART12.11 enhanced activation of the endocannabinoid and serotonergic systems in brain regions critical to mood regulation, including the prefrontal cortex, ventral hippocampus, and nucleus accumbens.

These results demonstrate ART12.11's potential as a differentiated therapeutic for mood and anxiety disorders – markets where limitations of conventional CBD, including inconsistent efficacy and poor bioavailability, have hindered clinical adoption. By addressing these shortcomings, ART12.11 may represent a significant advancement in cannabinoid-based therapeutics for anxiety and depression disorders, supporting Artelo's broader mission to bring novel, high-value and differentiated treatments to patients.

Professor Saoirse O'Sullivan, Vice President of Translational Sciences, commented, "We are pleased to see the publication of this important work demonstrating the impact of our

oral ART12.11 CBD cocrystal in stress-induced anxiety and depression. ART12.11's ability to improve stress-induced symptoms was not seen with CBD alone, the cocrystal coformer alone, or coadministration of CBD and the cocrystal conformer TMP. This shows the uniqueness of ART12.11."

Matt Jones, the lead researcher of this work at the University of Western Ontario, said, "In our recent study, we found that ART12.11 produced promising anti-depressant- and anti-anxiety-like effects. Our results suggest that ART12.11 works by selectively influencing serotonergic activity and endocannabinoid signaling – key pathways in mood regulation – while leaving other systems largely unaffected. This selectivity may help maximize therapeutic benefits while minimizing side effects."

Artelo recently disclosed that the MHRA, the regulatory authority in the UK, has agreed the Company may rely on the substantial body and sufficient nonclinical and clinical evidence for CBD. In addition, the agency affirmed Artelo may leverage the legacy data for TMP, which is expected to provide a scientifically justified basis for its clinical trial application. By streamlining the nonclinical development plan for ART12.11, the MHRA's guidance is anticipated to reduce costs and enable rapid advancement towards the proposed first human study with ART12.11 planned for next year.

About ART12.11

ART12.11 is Artelo's wholly owned, proprietary cocrystal composition of cannabidiol (CBD) and tetramethylpyrazine (TMP). Isolated as a single crystalline form, ART12.11 has exhibited better pharmacokinetics and improved efficacy compared to other forms of CBD in nonclinical studies. Greatly enhanced pharmaceutical properties, including physicochemical, pharmacokinetic, and pharmacodynamic advantages have been observed with ART12.11. Artelo believes a more consistent and improved bioavailability profile may ultimately lead to increased safety and efficacy in humans, thus making ART12.11 a preferred CBD pharmaceutical composition. The US issued composition of matter patent for ART12.11 is enforceable until December 10, 2038 and has now been granted or validated in 19 additional countries.

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 has adopted a forward-looking corporate finance initiative whereby it is deploying a portion of its excess capital into Solana under a newly authorized digital asset treasury strategy. As the first publicly traded pharmaceutical company to designate Solana as a core reserve asset, Artelo intends to leverage Solana's high-performance, decentralized blockchain to diversify its balance sheet, enhance liquidity management, and position the Company for long-term value creation in parallel with its therapeutic programs. Guided by disciplined risk controls and staged investments approved by the Board of Directors, this Solana-centric strategy is designed to preserve working capital for the continued advancement and commercialization of Artelo's product candidates while affording shareholders exposure to a next-generation monetary network. 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 strategies, clinical and regulatory timelines, market opportunity, competitive positions, 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

Source: Artelo Biosciences