

Artelo Biosciences Announces Positive Preclinical Efficacy with ART12.11 in Stress-Induced Depression Model

ART12.11, the Patented CBD:TMP Cocrystal, Demonstrates Potent Antidepressant-Like Activity and Cognitive Benefits Over Leading SSRI

Data Being Presented at the 35th Annual International Cannabinoid Research Society Symposium

SOLANA BEACH, Calif., July 07, 2025 (GLOBE NEWSWIRE) -- Artelo Biosciences, Inc. (Nasdaq: ARTL), a clinical-stage pharmaceutical company focused on modulating lipidsignaling pathways to develop treatments for people living with cancer, pain, dermatological or neurological conditions, today announced the presentation of compelling new preclinical data on its *Cannabidiol (CBD) and Tetramethylpyrazine (TMP)* cocrystal drug candidate, ART12.11, at the <u>35th Annual International Cannabinoid Research Society (ICRS)</u> Symposium, taking place July 6–10 in Bloomington, Indiana.

The poster, titled "ART12.11, A Novel Cannabidiol:Tetramethylpyrazine Cocrystal, Alleviates Stress-Induced Depressive Symptoms," is being presented today by Matt Jones, a scientist working in the laboratory of Professor Steven Laviolette at the University of Western Ontario, Canada. The data highlight ART12.11's unique dual-action profile in improving depression-related behaviors in animals and reversing cognitive deficits associated with chronic stress. These are key differentiators that position ART12.11 as a potential next-generation treatment candidate in the multi-billion-dollar antidepressant market.

Highlights:

- **Robust Antidepressant-like Effects:** A 28-day treatment regimen with ART12.11 significantly reversed behavioral impairments in male rats exposed to chronic stress. The data with ART12.11 demonstrated efficacy on par with sertraline (Zoloft), a leading selective serotonin reuptake inhibitor (SSRI).
- **Restoration of Hedonic and Social Behaviors:** Like sertraline, ART12.11 improved sucrose preference and social motivation, which are established behavioral markers of depressive-like states, to near-baseline levels.
- **Superior Cognitive Restoration:** Unlike sertraline, ART12.11 reversed stressinduced deficits in both spatial and short-term memory without negatively impacting social memory.
- Differentiated Therapeutic Profile: These findings underscore ART12.11's potential

as a highly differentiated candidate for treating depression and anxiety, especially in patients where cognitive dysfunction occurs, which is a known limitation of existing SSRI therapies.

"Our latest behavioral studies suggest that the cocrystal holds strong potential as a novel antidepressant. In a stressed rodent model, ART12.11 significantly restored key depression-related behaviors to baseline levels. The ability to experience pleasure and social motivation with ART12.11 were comparable to the effects of the established antidepressant sertraline. Notably, ART12.11 also reversed stress-induced cognitive impairments, which is an area where sertraline was not as effective," said Matt Jones, the lead researcher of this work at the University of Western Ontario.

Prior preclinical research studies in animals with ART12.11 demonstrated greater behavioral and pharmacokinetic results compared to CBD or Epidiolex. These new findings observed in Dr. Laviolette's laboratory are from the first preclinical study that compared ART12.11 to a leading SSRI.

"Although strong antidepressant effects were noted with ART12.11 in prior studies, we are especially encouraged by these comparative findings," said Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "We believe ART12.11 has the potential to meet a critical need in the mental health landscape by delivering both mood-lifting and cognitive benefits. which could set ART12.11 apart from existing antidepressants."

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. Superior 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. 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.

About the International Cannabinoid Research Society

The International Cannabinoid Research Society (ICRS) is the premier global scientific association with more than 650 international members from 40 countries, all active

researchers in the field of endogenous, plant-derived, and synthetic cannabinoids and related bioactive lipids. In addition to acting as a source for impartial information on cannabis and the cannabinoids, the main role of the ICRS is to provide an open forum for researchers to meet and discuss their research. The ICRS Symposium is being held July 6-10, 2025 in Bloomington, IN. Interested parties may follow <u>@ICRS_Society</u> on X.

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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