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Artelo Biosciences Receives Favorable UK MHRA Guidance for a Phase 1 Trial of ART12.11, the Company's Proprietary CBD:TMP Cocrystal Being Developed for the Treatment of Anxiety and Depression

MHRA indicated ART12.11 may be a candidate for accelerated development via the Innovative Licensing and Access Pathway

SOLANA BEACH, Calif., Aug. 01, 2025 (GLOBE NEWSWIRE) -- Artelo Biosciences, Inc. ("Artelo" or the "Company") **(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 that it has received written scientific advice from the UK's Medicines and Healthcare products Regulatory Agency (MHRA) on the nonclinical development and first-in-human (FIH) clinical study plans for ART12.11, a novel cocrystal of Cannabidiol (CBD) and Tetramethylpyrazine (TMP).

The MHRA agreed that reliance on the substantial body of historic nonclinical and clinical evidence for CBD, alongside legacy data for TMP, provides a scientifically justified basis for a streamlined clinical trial application (CTA)-enabling nonclinical development plan of the cocrystal combination to support the proposed FIH study, with clear guidance for achieving the agreed-upon FIH study design for ART12.11. The agency also affirmed that the proposed first-in-human (FIH) study design—a single-dose, multi-formulation crossover study—was methodologically sound for characterizing ART12.11's pharmacokinetic profile. Importantly, the MHRA offered constructive and specific guidance for completing the data package supporting the agreed-upon Phase 1 trial.

Additionally, the agency proposed that ART12.11 may be a candidate for the Innovative Licensing and Access Pathway (ILAP). ILAP offers a unique opportunity to accelerate the development and patient access of promising new therapies through early and sustained collaboration with the MHRA, National Health Service, and health technology assessment bodies. Given ART12.11's novel mechanism and potential to address unmet needs in anxiety and depression, Artelo believes the program aligns well with ILAP's criteria and will evaluate a formal application to enter the pathway in the coming months.

"It's gratifying to receive this positive feedback and actionable recommendations from the MHRA, which provides a clear path forward as we prepare to initiate clinical studies with ART12.11," said Dr. Andrew Yates, Chief Scientific Officer at Artelo. "The recommendation to explore ILAP reinforces the proposition of ART12.11 as a novel drug with the potential to

transform the treatment landscape for anxiety and depression."

Multiple nonclinical studies with ART12.11 have shown its promising profile compared to an antidepressant or CBD alone. The Company recently announced positive preclinical results in a depression model comparing ART12.11 with sertraline (Zoloft), a selective serotonin reuptake inhibitor (SSRI), where Artelo's patented CBD:TMP cocrystal demonstrated efficacy on par with sertraline and showed superior cognitive restoration compared to the leading SSRI. Additionally, in a rodent model of stress-induced anxiety and depression, where ART12.11 was compared to CBD dosed at 300% the amount of CBD contained in the oral tablet of ART12.11, the CBD:TMP cocrystal demonstrated efficacy where CBD alone did not.

"The clear regulatory assurance from the regulatory authority in the UK is expected to reduce expenses for our ART12.11 program," added Gregory Gorgas, President & CEO at Artelo. "We are especially pleased with the potential for an accelerated development strategy which could greatly accelerate our progress with ART12.11 and could provide for a longer period of market exclusivity as our patents are valid in 20 countries through the end of 2038. Over the next few months we look forward to finalizing our preparations to enter the clinic with ART12.11 early 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 in a solid dosage form may ultimately lead to increased safety and efficacy in humans, thus making ART12.11 a preferred CBD pharmaceutical composition. The U.S. 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 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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