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Artelo Biosciences Announces New Data on ART12.11 Tablets Showing Improved Pharmacokinetics to Epidiolex®

SOLANA BEACH, Calif., Feb. 14, 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 nonclinical results on ART12.11, its proprietary cocrystal composition of cannabidiol (CBD) and tetramethylpyrazine (TMP). The findings were presented by Professor Saoirse O'Sullivan, Vice President of Translational Science at Artelo Biosciences, at the International Medical Cannabis Conference (IMCCB-25), held February 13-14, 2025, at the University of Bern, Switzerland.

Professor O'Sullivan's presentation, "A Cannabidiol Cocrystal (ART12.11) Tablet Has Comparable Pharmacokinetics to Epidiolex," highlighted results from canine studies evaluating Artelo's oral solid formulations of ART12.11 against the liquid formulation of Epidiolex®, the only FDA-approved CBD therapy. The studies showed that two different tablet formulations of ART12.11 achieved CBD and metabolite exposure levels similar or greater to the equivalent dose of Epidiolex, supporting the potential of ART12.11 as an alternative formulation of CBD.

Solid-dose formulations, such as tablets, may have certain advantages including improved stability, ease of dosing, lower cost-of-goods or enhanced patient adherence. Cocrystallization, a pharmaceutical approach to improving drug solubility and bioavailability, plays a key role in ART12.11's formulation, addressing challenges associated with CBD's physical properties, enabling the manufacture of a simple compression tablet with high drug loading. Artelo is evaluating multiple tablet prototypes of ART12.11, each containing 100mg of CBD with the potential to increase the drug loading further.

"We are highly encouraged by these results, which reinforce our belief in ART12.11's potential as a commercially attractive advancement compared to existing CBD formulations or those in development," said Andrew Yates, Senior Vice President and Chief Scientific Officer at Artelo. "As a proprietary cocrystal of CBD and TMP, ART12.11 has demonstrated improved pharmacokinetics, enhanced efficacy, and significant pharmaceutical advantages in nonclinical studies. Tableted ART12.11 offers a patent-protected, scalable, and low-cost approach for developing CBD as a tablet in conditions previously seen as out-of-scope with CBD's current pharmaceutical limitations. We look forward to exploring ART12.11's advantages further as we progress into human studies."

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. Significantly 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.

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 IMCCB-25

The IMCCB-25 seeks to inform participants about the latest evidence and concepts regarding cannabis- and cannabinoid-based therapies. It aims to assist prescribers in practically implementing best practices based on current research, expert opinions and therapy guidelines. The IMCCB-25 conference covers a broad spectrum of topics, including basic and clinical methodologies, safety, analytics, pharmaceuticals, regulatory and legal considerations, pharmacological insights, and technological advancements. The emphasis is on practical implications for patients, researchers, medical persons, and industry leaders alike. Additional topics include palliative care, women medicine, psychiatry and geriatric diseases, niche indications as well as non-medical cannabis use disorders. More information about IMCCB-25 can be found at <https://www.imccb.org>

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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