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Artelo Biosciences Announces Promising New Data on Novel Non-Opioid Treatment Approach for Osteoarthritis Pain at the 13th Annual Musculoskeletal Repair and Regeneration Symposium

ART26.12, the Company's Lead Clinical Fatty Acid Binding Protein 5 Inhibitor, Continues to Show Positive Preclinical Results in Multiple Pain Studies

SOLANA BEACH, Calif., Nov. 13, 2024 (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 and neurological conditions, announced new data being presented today on ART26.12, Artelo's lead clinical Fatty Acid Binding Protein 5 (FABP5) inhibitor, in osteoarthritis (OA) pain at the 13th Annual Musculoskeletal Repair and Regeneration Symposium in New York. This evidence adds OA pain to the list of pain types such as neuropathic and cancer bone pain where ART26.12 has shown potential as an analgesic with a novel mechanism of action.

In this new research conducted at Stony Brook University, ART26.12 demonstrated more responsive symptom relief in a surgical rodent OA model than naproxen, a commonly used nonsteroidal anti-inflammatory drug (NSAID) in the treatment of OA. ART26.12 significantly improved weight-bearing on affected limbs at all three doses studied, indicating a reduction in OA-induced pain. Importantly, ART26.12 demonstrated a clear dose-response relationship, with higher concentrations yielding greater pain relief and more rapid responses than naproxen.

The study, entitled "Fatty Acid Binding Protein 5 Inhibitor, ART26.12, is a Novel Analgesic for Osteoarthritis Pain," was conducted by the Department of Orthopedics and Rehabilitation and the Department of Anesthesiology at the Renaissance School of Medicine at Stony Brook University by Drs. Kai Bou, Adam Bruzzese, Kaitlin Farrell, Chris Gordon, David Komatsu and Martin Kaczocha. "We are encouraged by these behavioral data showing efficacy for ART26.12 in alleviating osteoarthritis pain," said Dr. Komatsu of Stony Brook University. "Furthermore, we are dedicated to completing our remaining analyses to gain a comprehensive understanding of the biological response to this promising compound."

According to the World Health Organization, OA affects over 500 million people globally.

Symptoms of OA include joint debilitation and persistent, extreme pain. Artelo's research continues with a focus on long-term efficacy, currently evaluating the effects of four weeks of repeated dosing of ART26.12 on pain behaviors as well as knee structures and joint degradation. ART26.12 operates through a novel lipid-signaling pathway by inhibiting FABP5, which reduces cytokine and chemokine expression linked to OA pain. Preclinical efficacy has already been seen in both single and repeat dosing scenarios suggesting potential for both acute and chronic OA pain management.

Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences, added, "This new OA research constitutes our seventh preclinical study in pain, all of which show ART26.12's potential as an innovative alternative to NSAIDs and opioids for some of the most severe pain management challenges."

The U.S. Food and Drug Administration (FDA) cleared ART26.12 to initiate for its first-in-human Phase 1 single ascending dose study with initial results anticipated during the first half of 2025. As previously reported, ART26.12 has also been accepted into the NIH Helping to End Addiction Long Term Initiative's Preclinical Screening Platform for Pain which seeks to accelerate development of non-opioid, non-addictive treatment options for pain management.

About ART26.12

ART26.12, Artelo's lead Fatty Acid Binding Protein 5 (FABP5) cleared by the FDA to initiate first-in-human studies, is a potent and selective inhibitor of FABP5 being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic, with initial clinical development planned for chemotherapy-induced peripheral neuropathy (CIPN). Fatty Acid Binding Proteins (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 a number of pathologies. Beyond ART26.12 in CIPN, Artelo's extensive 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.

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.

About Stony Brook University

Stony Brook University, New York's flagship university and No. 1 public university, was established in 1957 as a college for the preparation of secondary school teachers of mathematics and science. Stony Brook is part of the State University of New York (SUNY) system. The university has grown tremendously and is now recognized as one of the nation's important centers of learning and scholarship.

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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