December 9, 2024

Artelo Biosciences Announces Presentation of Phase 1 Data with ART27.13 in Cancer-Related Anorexia

Phase 1 data from the CAReS trial showed an attractive safety profile and promising activity from daily ART27.13 administration with two-thirds of participants having stabilized or reversed weight loss at one month of treatment

SOLANA BEACH, Calif., Dec. 09, 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, today announced the presentation of preliminary data on ART27.13, the Company's benzimidazole derivative, being studied for cancer-related anorexia. The data was presented by the Principal Investigator, Professor Barry J. A. Laird, Chair of Palliative and Supportive Care, University of Edinburgh and Consultant Physician in Palliative Medicine, Edinburgh Cancer Centre, at the 17th International Conference on Sarcopenia, Cachexia, & Wasting Disorders, held December 6-8, 2024 in Washington D.C.

Artelo is evaluating ART27.13 in the Cancer Appetite Recovery Study (CAReS), a randomized, placebo-controlled Phase 1/2 trial in cancer-related anorexia, which is currently enrolling the Phase 2 of the study. In the Phase 1 of CAReS, ART27.13 was orally administered at 150 to 650 microgram doses in multiple centers throughout the UK and Ireland. The investigational drug was well tolerated with only mild to moderate adverse events observed in a minority of participants. No serious or life-threatening adverse events were recorded. Importantly, at one month of treatment, two-thirds of participants showed evidence the drug was impacting their weight loss with either stabilization or reversal of weight loss associated with their cancer.

"With no therapies approved to treat cancer-related anorexia in the UK, US, or Europe, I am impressed by the effect of ART27.13 at low doses in the majority of the participants in CAReS," commented Prof. Laird of the University of Edinburgh. "The results are particularly encouraging in these advanced cancer patients where the highest dose evaluated in the initial study was found to be well tolerated and was advanced for further evaluation as the starting dose in Phase 2."

Open to enrollment in fifteen sites across five countries, the Phase 2 of CAReS is accruing participants at a 650 microgram dosage with planned escalation at 4-week intervals up to a dose of 1300 micrograms per day. In CAReS, all participants receive ART27.13 once-daily for up to 12 weeks and the endpoints include lean body mass, weight gain, quality of life and

safety. The Phase 2 portion will also evaluate any impact on activity levels using a monitor attached to the patient's wrist. The study is expected to complete enrollment during the first half of 2025.

Steven D. Reich, MD, Chief Medical Officer of Artelo Biosciences, added, "ART27.13 has the potential to become a major drug for the treatment of loss of appetite and weight in patients with cancer. As previously reported, preclinical research with ART27.13 showed the drug was protective against myotube degeneration in cancer cachexia conditions. The addition of a wearable monitor may show improved activity believed to be attributable to protection against muscle loss. We look forward to evaluating the results of the full study next year."

About ART27.13

ART27.13 is a benzimidazole derivative being developed as a once-a-day, orally administered drug to improve body weight, appetite, muscle degeneration, and quality of life in cancer patients. This new chemical entity is a highly potent, peripherally restricted, CB_1 and CB_2 receptor agonists. Originally developed by AstraZeneca plc, ART27.13 has been in clinical studies with over 250 participants. A statistically significant and dose-dependent increase in body weight was observed in patients with back pain who were otherwise healthy. Importantly, the drug enables systemic metabolic effects while minimizing central nervous system-mediated toxicity. Having completed a Phase 1 study in cancer patients where ART27.13 demonstrated an attractive safety profile, ART27.13 is now being investigated in a placebo-controlled phase 2 in cancer patients suffering from anorexia and weight loss. Currently, there is no FDA- or EMA-approved treatment for cancer anorexia cachexia syndrome.

About CAReS

The Cancer Appetite Recovery Study (CAReS) (carestrial.com) is a Phase 1/2 randomized, placebo-controlled trial of the Company's clinical program, ART27.13, in patients with cancer anorexia and weight loss. Cancer-related anorexia, or the lack or loss of appetite in the person with cancer, may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for people with cancer to lose weight. Anorexia and the resulting weight loss can affect a patient's health, often weakening their immune system and causing discomfort and dehydration. A weight loss of more than five percent can predict a poor outcome for cancer patients and a lower response to chemotherapy. Now completed, the Phase 1 portion of the CAReS study was designed to determine a safe starting dose of ART27.13 for dosing in the Phase 2 portion of the study. Currently enrolling, the Phase 2 portion of the CAReS study is designed to determine estimates of activity of ART27.13 versus placebo in terms of lean body mass, weight gain, and improvement of anorexia and activity. (ISRCTN registry: https://www.isrctn.com/ISRCTN15607817)

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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Source: Artelo Biosciences