NEWS RELEASE

Assertio Announces Publication of Rolvedon® Same-Day Dosing Clinical Trial

2026-01-09

Peer-reviewed publication in “The Oncologist” is now available online

Investigational same-day dosing of Rolvedon demonstrated a clinical response and adverse event profile similar to next-day dosing

LAKE FOREST, Ill.--(BUSINESS WIRE)-- Assertio Holdings, Inc. (“Assertio” or the “Company”) (Nasdaq: ASRT) today announced that results of a clinical trial investigating a novel dosing schedule of Rolvedon® (eflapegrastim-xnst) injection have been peer reviewed and **published** in The Oncologist.

In the study of patients with early-stage breast cancer (ESBC), Rolvedon, when administered on the same day (same-day dosing) as TC chemotherapy (Taxotere (docetaxel) and cyclophosphamide) demonstrated an effective neutrophil recovery and an adverse event profile similar to that seen with next-day dosing.

Howard Franklin, M.D., Senior Vice President of Medical with Assertio: “We were encouraged to see that same-day dosing of Rolvedon demonstrated efficacy and safety similar to dosing one day after chemotherapy. Assertio is proud to lead this study that provides data that supports a more convenient administration schedule for Rolvedon. Thank you to the investigators and patients who participated in this study.”

Lee Schwartzberg, M.D., Professor of Clinical Medicine with Renown Health-Pennington Cancer Institute, Reno, Nevada, and a study author: “Febrile neutropenia (FN) is a significant risk factor among patients with early-stage breast cancer who are undergoing chemotherapy. This important study provides the oncology community with much-needed insight into the potential utility of same-day dosing of GCSF therapy with Rolvedon in these patients.”

The Oncologist is the official peer-reviewed medical journal for the Society for Translational Oncology. Results of this study were first presented in December 2024 as part of the San Antonio Breast Cancer Symposium.

Study Summary

This phase 1, multicenter (13 sites in the U.S.), open-label trial (NCT04187898) evaluated the efficacy and safety of Rolvedon administered on the same day as TC chemotherapy in patients (n = 53) with ESBC. Patients received four cycles of TC chemotherapy with Rolvedon administered at 30 minutes after TC. The primary endpoint was the time to recovery of absolute neutrophil count (ANC) from nadir to ≥1.5 × 109/L in Cycle 1. The ANC is a blood test that measures the number of circulating neutrophils, a type of white blood cell essential for fighting infections. Normal ANC indicates a healthy immune response, while low levels (neutropenia) can increase the risk of infections.

Secondary study endpoints included safety, incidence of severe neutropenia, duration of severe neutropenia, incidence of FN, and neutropenic complications.

A total of 53 patients enrolled; 49 completed the study. Patients received the recommended 13.2 mg (3.6 mg GCSF) fixed-dose of Rolvedon 30 min following TC chemotherapy. The mean time to ANC recovery was 1.8 days in cycle 1. The incidence of FN was low, reported in only 1 patient during the entire trial. There were no reported neutropenic complications, with no patients requiring hospitalization and/or antibiotic therapy. Same-day administration of Rolvedon was well tolerated and no new safety signals were observed.

The benefits of eflapegrastim-xnst given same day as TC have not been evaluated in a randomized controlled trial.

About Assertio

Assertio is a pharmaceutical company with comprehensive commercial capabilities offering differentiated products designed to address patients' needs. Our focus is on supporting patients by marketing products in oncology, neurology, and pain management. To learn more about Assertio, visit **www.assertiotx.com.**

About Rolvedon (eflapegrastim-xnst) Injection

ROLVEDON (eflapegrastim-xnst) injection is a long-acting granulocyte colony-stimulating factor (G-CSF) with a novel formulation. Rolvedon is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Assertio has designated Rolvedon as one of the company's core growth assets.

Please see the Important Safety Information below and the full prescribing information for ROLVEDON at **https://www.rolvedon.com/pdf/rolvedon-prescribing-information.pdf.**

Limitations of Use

ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Contraindications

- ROLVEDON is contraindicated in patients with a history of serious allergic reactions to eflapegrastim, pegfilgrastim or filgrastim products. Reactions may include anaphylaxis.

Warnings and Precautions

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of recombinant human granulocyte colony-stimulating factor (rhG-CSF) products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving rhG-CSF products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue ROLVEDON in patients with ARDS.

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving rhG-CSF products. Permanently discontinue ROLVEDON in patients who experience serious allergic reactions.

Sickle Cell Crisis in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving rhG-CSF products. Discontinue ROLVEDON if sickle cell crisis occurs.

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving rhG-CSF products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation. Evaluate and consider dose reduction or interruption of ROLVEDON if causality is likely.

Leukocytosis

- White blood cell (WBC) counts of 100 x 109/L or greater have been observed in patients receiving rhG-CSF products. Monitor complete blood count (CBC) during ROLVEDON therapy. Discontinue ROLVEDON treatment if WBC count of 100 x 109/L or greater occurs.

Thrombocytopenia

- Thrombocytopenia has been reported in patients receiving rhG-CSF products. Monitor platelet counts.

Capillary Leak Syndrome

- Capillary leak syndrome has been reported after administration of rhG-CSF products and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency and severity and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor and give standard symptomatic treatment, which may include a need for intensive care.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- The granulocyte colony-stimulating factor (G-CSF) receptor through which ROLVEDON acts has been found on tumor cell lines. The possibility that ROLVEDON acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which ROLVEDON is not approved, cannot be excluded.

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

- MDS and AML have been associated with the use of rhG-CSF products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

Aortitis

- Aortitis has been reported in patients receiving rhG-CSF products. It may occur as early as the first week after start of therapy. Consider aortitis in patients who develop generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white

blood cell count) without known etiology. Discontinue ROLVEDON if aortitis is suspected.

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

Adverse Reactions

- The most common adverse reactions (≥20%) were fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.
- Permanent discontinuation due to an adverse reaction occurred in 4% of patients who received ROLVEDON. The adverse reaction requiring permanent discontinuation in 3 patients who received ROLVEDON was rash.

To report SUSPECTED ADVERSE REACTIONS, contact Assertio Holdings, Inc. at 1-866-458-6389 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch.**

Forward-Looking Statements

Statements in this communication that are not historical facts are forward-looking statements that reflect Assertio's current expectations, assumptions and estimates of future performance and economic conditions. These forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements relate to, among other things, future events or the future performance or operations of Assertio, including risks related to our ability to realize the benefits from our operating model, deliver or execute on our business strategy, including to expand or diversify our asset base and market reach and drive cash flows and growth, successfully integrate new assets, and explore new business development initiatives. All statements other than historical facts may be forward-looking statements and can be identified by words such as "anticipate," "believe," "could," "design," "estimate," "expect," "forecast," "goal," "guidance," "imply," "intend," "may," "objective," "opportunity," "outlook," "plan," "position," "potential," "predict," "project," "prospective," "pursue," "seek," "should," "strategy," "target," "would," "will," "aim" or other similar expressions that convey the uncertainty of future events or outcomes and are used to identify forward-looking statements. Such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, some of which are beyond the control of Assertio, including the risks described in Assertio's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in other filings Assertio makes with the SEC from time to time.

Investors and potential investors are urged not to place undue reliance on forward-looking statements in this communication, which speak only as of this date. While Assertio may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by applicable law.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20260109405279/en/**

Investor and Media Contact
Longacre Square Partners
assertio@longacresquare.com

Source: Assertio Holdings, Inc.