# Viatris Announces Publication of Phase 2b CARE Study Data for Cenerimod in Lancet Rheumatology

December 18, 2024

*Biomarker data from CARE study characterizing cenerimod's mechanism of action in systemic lupus erythematosus also published in the Annals of the Rheumatic Diseases*

PITTSBURGH, Dec. 18, 2024 /PRNewswire/ -- **Viatris Inc.** (NASDAQ: VTRS) today announced the publication of Phase 2b CARE study results evaluating the efficacy and safety of cenerimod in adults with moderate-to-severe systemic lupus erythematosus (SLE). The results, published in *Lancet Rheumatology*[i], showed cenerimod 4 mg demonstrated clinically meaningful and sustained improvement from baseline on multiple measures of SLE disease activity compared to placebo, in addition to stable background SLE therapy. Cenerimod was shown to be well tolerated with an adverse event profile consistent with the mechanism of action.

In addition, results from the analysis of the CARE study on SLE-related biomarker data were published in the *Annals of the Rheumatic Diseases*[ii] and further characterized the mechanism of action of cenerimod in patients living with SLE.

"We are pleased our Phase 2b CARE study results were published in two prominent journals, *Lancet Rheumatology* and *Annals of the Rheumatic Diseases*, which underscores the urgent need for novel agents for the treatment of SLE, like cenerimod," said Viatris Chief R&D Officer **Philippe Martin**. "The biomarker data highlights the multifaceted immunomodulatory properties of cenerimod targeting key aspects of SLE pathogenesis."

This data informed the design and dose selection of the ongoing Phase 3 OPUS program (OPUS-1 NCT05648500, OPUS-2 NCT05672576, OPUS-OLE NCT06475742).

The CARE study was a double-blind, randomized, placebo-controlled, Phase 2b trial in adults aged 18-75 years old with moderate-to-severe SLE. Out of the 810 patients screened, 427 were randomly assigned (1:1:1:1:1) to once-daily oral cenerimod at 0.5 mg, 1 mg, 2 mg, or 4 mg or placebo, in addition to stable background SLE therapy, and followed up for 12 months. The primary endpoint was change from baseline to month 6 in mSLEDAI-2K score of cenerimod versus placebo.

**CARE Study Results:**

- At month 6, the maximum response was observed within the 4 mg group with least squares mean change from baseline in mSLEDAI-2K score being -4.04 (95% CI -4.79 to -3.28; difference vs placebo -1.19 [-2.25 to -0.12]; p=0.029).
- Furthermore, in a subgroup analysis, patients with a high IFN-1 gene expression signature treated with cenerimod 4 mg showed greater reduction in mSLEDAI-2K at month 6 at -2.78 as compared to placebo. Also, 24% higher SRI-4 response rate was seen as compared to placebo in this subgroup.
- Cenerimod 4 mg significantly reduced IFN-γ-associated proteins in addition to IFN-1 protein and gene expression signature biomarkers after 6 months of treatment when compared to placebo, with an overall larger effect size in the IFN-1 high patients. This data supports the stronger clinical response observed in the IFN-1 high population in the CARE study.
- Over 12 months of treatment and the follow-up period, most adverse events (AEs) were mild to moderate and there were no serious adverse events (SAEs) related to cenerimod. Cenerimod was considered to be generally well tolerated at all doses evaluated.

The abstract of the publication within *Lancet Rheumatology* titled, *Cenerimod, a sphingosine-1-phosphate receptor modulator, versus placebo in patients with moderate-to-severe systemic lupus erythematosus (CARE): an international, double-blind, randomised, placebo-controlled, Phase 2 Trial*, can be accessed **here**.

The full manuscript of the publication within *Annals of the Rheumatic Diseases* titled, *Pharmacodynamics of the $S1P_1$ receptor modulator cenerimod in a phase 2b randomised clinical trial in patients with moderate to severe SLE*, can be accessed **here**.

**About SLE**
Systemic lupus erythematosus (SLE), the most common form of lupus, is an autoimmune disease. SLE is a complex autoimmune disease characterized by the aberrant activity of the immune system and includes lymphocyte activation, autoantibody production, activation of inflammatory cytokine pathways and improper clearance of apoptotic cells with consequent immune complex deposition.

**About cenerimod**
Cenerimod is an investigational drug, a highly selective $S1P_1$ receptor modulator given as an oral once-daily tablet that targets SLE pathogenesis

through immunomodulatory effects on lymphocytes, inflammation and antigen transport. Cenerimod is an investigational drug that potentially offers a novel approach for the treatment of SLE, a disease with a significant impact on patients and limited treatment options.

Cenerimod reduces circulating and tissue-infiltrating lymphocytes, systemic and local inflammation, autoantibodies, and auto-antigen transport to lymph nodes, leading to decreased T-cell priming and proinflammatory cytokine secretion resulting in improved disease activity.[i]

In December 2022, the Oral S1P$_1$ receptor ModUlation in SLE (OPUS) program was initiated, which consists of two multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 3 studies to evaluate the efficacy, safety, and tolerability of cenerimod in adult patients with moderate-to-severe SLE on top of background therapy. The main objectives of the program are to evaluate the effectiveness of cenerimod 4 mg in reducing disease activity, as well as controlling the disease, compared to placebo. The primary endpoint is response on SRI-4 at month 12 compared to baseline. Secondary endpoints include response on BICLA at month 12 compared to baseline and measures of sustained disease control: time to first confirmed 4-month sustained mSLEDAI-2K response and time to first confirmed 4-month sustained response in mucocutaneous manifestations (i.e., rash, alopecia, mucosal ulcers).

The investigation of cenerimod for the treatment of SLE has received Fast-Track designation from the U.S. Food and Drug administration (FDA). This designation is intended to promote communication and collaboration between the FDA and pharmaceutical companies for drugs that treat serious conditions and fill an unmet medical need.

**About the CARE Study**
CARE was a Phase 2b, multicenter, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy, safety, and tolerability of cenerimod in subjects with moderate to severe systemic lupus erythematosus (SLE). Patients with SLE, mSLEDAI-2K ≥6 and history or presence of positive ANA or anti-dsDNA were randomized to daily oral cenerimod (0.5, 1, 2 or 4 mg) or PBO. Background SLE medication had to be stable for ≥30 days pre-randomization (corticosteroids ≥15 days). Study duration was 18 months (M), two 6M treatment periods and a 6M follow-up. After the first 6M, patients on cenerimod 4 mg were rerandomized to cenerimod 2 mg or PBO to assess reversibility of lymphopenia and potential withdrawal effects. Of 427 randomized patients, 339 completed 12M of treatment. The primary endpoint was change from baseline (BL) to M6 in mSLEDAI-2K. Secondary endpoints were SLE Responder Index SRI-4 and BILAG-2004 improvement. Safety endpoints included adverse events (AEs) and AEs of special interest (AESI).

**About Viatris**
**Viatris Inc.** (NASDAQ: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, currently supplying high-quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at **viatris.com** and **investor.viatris.com,** and connect with us on **LinkedIn**, **Instagram**, **YouTube** and **X** (formerly Twitter).

**Forward-Looking Statements**
This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward looking statements may include statements regarding the outcomes of clinical trials and product development timelines. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market, including but not limited to "at-risk" launches; Viatris' or its partners' ability to develop, manufacture, and commercialize products; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings; the possibility that Viatris may be unable to realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives; the possibility that Viatris may be unable to achieve intended or expected benefits, goals, outlooks, synergies, growth opportunities and operating efficiencies in connection with divestitures, acquisitions, other transactions or restructuring programs, within the expected timeframes or at all; goodwill or impairment charges or other losses related to the divestiture or sale of businesses or assets; Viatris' failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties and matters beyond the control of management, including general economic conditions, inflation and exchange rates; failure to execute stock repurchases consistent with current expectations; stock price volatility; and the other risks described in Viatris' filings with the Securities and Exchange Commission (SEC). Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this press release other than as required by law.


[i] Cenerimod, a sphingosine-1-phosphate receptor modulator, versus placebo in patients with moderate-to-severe systemic lupus erythematosus (CARE): an international, double-blind, randomised, placebo-controlled, phase 2 trial. Askanase, Anca D et al. The Lancet Rheumatology. Published Online November 22, 2024 https://doi.org/10.1016/S2665-9913(24)00246-7

[ii] Suffiotti M, Brazauskas P, Keller MP, et al. Pharmacodynamics of the S1P1 receptor modulator cenerimod in a phase 2b randomized clinical trial in patients with moderate to severe SLE. Annals of the Rheumatic Diseases Published Online First: 24 November 2024. doi: 10.1136/ard-2024-226547

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