Viatris Presents Late Breaking Abstract on Cenerimod at the 26th Asia-Pacific League of Associations for Rheumatology Annual Congress

August 23, 2024

Late-Breaking oral presentation shows that cenerimod for the treatment of moderate to severe systemic lupus erythematosus (SLE) in Japanese patients can be considered safe and well-tolerated

Data shows a clinically meaningful improvement in disease activity consistent with results from other global Phase 2 studies of cenerimod

PITTSBURGH, Aug. 23, 2024 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, presented today the results of one of its Phase 2 studies* of cenerimod (ACT-333441). The ACT-333441 study was accepted as a late-breaking abstract and was presented during an oral presentation at the 26th Asia-Pacific League of Associations for Rheumatology (APLAR) Annual Congress. The congress is being held August 21-25, 2024, in Suntec, Singapore.

The ACT-333441 study was a randomized, double-blind, parallel-group, multicenter, Phase 2 study that was conducted in Japan and evaluated the safety, pharmacodynamics (PD), and efficacy of cenerimod, a selective $S1P_1$ receptor modulator, in 17 Japanese patients with moderate to severe systemic lupus erythematosus (SLE). Adult patients receiving SLE background treatment were randomized equally to either 2 mg or 4 mg cenerimod (once-daily, oral dosing). The primary endpoint of the study measured safety and tolerability, and the secondary endpoint measured a change in total lymphocyte count and the efficacy was assessed using a modified SLEDAI-2K (mSLEDAI-2K) score.

Both cenerimod doses were considered safe and well-tolerated. A decrease in lymphocyte counts was observed in both the 2 mg and 4 mg doses as expected per the mechanism of action of cenerimod and was reversible upon treatment discontinuation. Both doses showed a clinically meaningful improvement in disease activity, as measured by mSLEDAI-2K, which persisted long after the treatment was discontinued and was higher with the 4 mg dose. These results are generally consistent with the global Phase 2 CARE study*.

Visit Viatris at APLAR at Booth #21-23 to learn more about the study and how the company continues to support the needs of the SLE community. The data was presented during the following oral presentation:

- **Cenerimod in Japanese patients with moderate to severe systemic lupus erythematosus (SLE): A Phase 2, randomized, double-blind trial**
  - Speaker: Sharavan Kanagaratnam
  - August 23, 3:00 - 4:15 p.m. GMT+8
  - Abstract session 3: Late-breaking abstracts: Systemic lupus erythematosus

Further details on the APLAR program can be accessed online here.

About SLE
Systemic lupus erythematosus (SLE), the most common form of lupus, is an autoimmune disease. While the cause of SLE is not fully known, T and B lymphocytes are considered the key immune cells that play a role in the development of SLE. In individuals with SLE, both T and B cells become overactive, infiltrate different tissues, and produce autoantibodies, leading to inflammation and organ damage.

About cenerimod
Cenerimod is an investigational drug, a highly selective $S1P_1$ receptor modulator given as an oral once-daily tablet. 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.

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; that late-breaking oral presentation shows that cenerimod for the treatment of moderate to severe systemic lupus erythematosus (SLE) in Japanese patients can be considered safe and well-tolerated; that data shows a clinically meaningful improvement in disease activity consistent with results from other global Phase 2 studies of cenerimod; that both cenerimod doses were considered safe and well-tolerated; that a decrease in lymphocyte counts was observed in both the 2 mg and 4 mg doses as expected per the mechanism of action of cenerimod and was reversible upon treatment discontinuation; and that both doses showed a clinically meaningful improvement in disease activity, as measured by mSLEDAI-2K, which persisted long after the treatment was discontinued and was higher with the 4 mg dose. 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.

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