Viatris Announces Positive Top-Line Results from Phase 3 Study of VR-205 in Japanese Adults with Primary Immunoglobulin A Nephropathy

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VR-205 Met Primary Endpoint and Key Secondary Endpoints and Was Well Tolerated

VR-205 Efficacy and Safety Profile in Japanese Patients Was Consistent with the Profile Observed in Global Studies

Japanese New Drug Application Submission Targeted by End of 2026

PITTSBURGH and TOKYO, June 29, 2026 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced positive top-line results from a Phase 3 clinical trial evaluating the efficacy and safety of VR-205 (targeted-release budesonide formulation) (Nefecon®) in Japanese adult patients with primary immunoglobulin A nephropathy (IgAN) at risk of developing end-stage renal disease.

The Phase 3 clinical trial was a multicenter, interventional, open-label study designed to evaluate the efficacy and safety of 16 mg of VR-205 in Japanese adult patients with primary IgAN. Patients were treated for nine months, followed by a three-month follow-up period.

The study achieved its primary endpoint, with VR-205 demonstrating a 33.75 percent reduction in geometric mean urine protein-to-creatinine ratio (UPCR) at 9 months compared to baseline [95% CI: -45.27 to -19.80; $p < 0.001$]. These results were statistically significant and clinically meaningful, and were consistent with those observed in the global Phase 3 program for the product. Key findings included:

- In addition to a statistically significant and clinically meaningful reduction in UPCR at 6 and 12 months, VR-205 demonstrated a significant improvement in estimated glomerular filtration rate (eGFR) and reductions in serum creatinine and urine albumin-to-creatinine ratio (UACR) at 9 months compared to baseline.
- The overall therapeutic benefit of VR-205 was further supported by improvements in microhematuria and a sustained proteinuria reduction.
- No study participants progressed to dialysis, kidney transplant or severe renal impairment (eGFR ≤15 mL/min per 1.73 m^2) by the end of the study.
- VR-205 was generally well tolerated over the nine-month treatment period, with a safety profile consistent with the known safety profile of targeted-release budesonide in non-Japanese patients.

"We are pleased with these top-line results, which highlight VR-205 as a potentially meaningful, disease-modifying treatment option for patients with primary IgAN," said Viatris Chief R&D Officer **Philippe Martin**. "In Japan, where IgAN incidence is the highest globally, VR-205 could become the first IgAN-specific, targeted-release budesonide oral therapy. This progress reflects the continued execution of Viatris' strategy focused on building a differentiated and increasingly innovative portfolio in Japan, with an emphasis on delivering therapies that provide meaningful value and address significant unmet needs."

"Primary IgAN is a designated intractable disease in Japan, and remains a significant unmet need, with no curative treatment despite the risk of progression to end-stage renal disease," said Yuko Asami, Head of R&D, Viatris Japan. "These top-line results mark an important step toward expanding treatment options for patients and healthcare providers."

Viatris is targeting submission of a New Drug Application in Japan by the end of 2026.

In 2022, Calliditas Therapeutics AB and Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc., entered into an exclusive license agreement to obtain marketing authorization and to commercialize VR-205 for the treatment of primary IgAN in Japan. It is currently a specialty drug approved and marketed as Tarpeyo® in the U.S. and as Kinpeygo® in Europe.

About Phase 3 Study (VR-205A-01-CAZ-3001)
The Phase 3 trial was a multicenter, interventional, open-label study conducted in Japan to evaluate the efficacy and safety of oral VR-205 (targeted-release budesonide formulation) for the treatment of primary IgA nephropathy in Japanese adult patients at risk of developing end-stage renal disease. The study enrolled a total of 39 participants who were treated with 16 mg of VR-205 daily (four capsules) over a nine-month treatment period.

Following completion of treatment, participants entered a three-month follow-up period including a two-week dose tapered to 8 mg of VR-205 (two capsules) daily at the start of the follow-up period.

About Immunoglobulin A Nephropathy (IgAN)
IgAN is a progressive, immune-mediated kidney disease and the most common primary glomerulonephritis worldwide. Japan reports the highest incidence rates globally, at 39 to 45 cases per million population per year, with peak age at diagnosis between 30 and 39 years. In Japan, adult-onset IgAN is reported to progress to end-stage renal disease (dialysis or transplantation) in approximately 15-20 percent of patients within 10 years. Most patients reaching end-stage renal disease face decades of dialysis. The total national cost of maintenance hemodialysis in Japan is approximately

JPY 1.5 trillion per year. Chronic glomerulonephritis (with IgAN as a leading underlying cause) accounts for 23.4 percent of Japan's more than 340,000 dialysis patients. Despite this burden, therapies that target the underlying immunological drivers of IgAN to preserve long-term kidney function have remained limited, and a clear need persists for disease-modifying treatment options.

About Viatris

Viatris Inc. (Nasdaq: VTRS) is a global healthcare company whose mission is to empower people worldwide to live healthier at every stage of life. We meet the needs of patients around the world by acting decisively with ingenuity and resolve. Whether we're developing new medicines, working to maintain a resilient supply of needed therapies, or pursuing bold innovation, we strive to deliver solutions that are effective at scale and built to endure. We're purpose-built to make an impact with a dynamic portfolio that spans generics, established brands and innovative medicines that address areas of significant unmet need. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai, China, and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on LinkedIn, Instagram, YouTube and X.

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 that positive top-line results from a Phase 3 clinical trial evaluating the efficacy and safety of VR-205 (targeted-release budesonide formulation) (Nefecon®) in Japanese adult patients with primary immunoglobulin A nephropathy (IgAN) at risk of developing end-stage renal disease; VR-205 met primary endpoint and key secondary endpoints, and was well tolerated; VR-205 efficacy and safety profile in Japanese patients was statistically significant and clinically meaningful and were consistent with the profile observed in global studies; we are pleased with these top-line results, which highlight VR-205 as a potentially meaningful, disease-modifying treatment option for patients with primary IgAN; in Japan, where IgAN incidence is the highest globally, VR-205 could become the first IgAN-specific, targeted-release budesonide oral therapy; this progress reflects the continued execution of Viatris' strategy focused on building a differentiated and increasingly innovative portfolio in Japan, with an emphasis on delivering therapies that provide meaningful value and address significant unmet needs; these top-line results mark an important step toward expanding treatment options for patients and healthcare providers; Viatris is targeting submission of a New Drug Application in Japan by the end of 2026. 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: the uncertainties inherent in research and development, including the outcomes of clinical trials; the ability to meet anticipated clinical endpoints; the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from clinical studies; failure to achieve the intended benefits of our strategic initiatives and priorities; goodwill or impairment charges or other losses; any changes in or difficulties with the Company's manufacturing facilities; failure to achieve expected or targeted future financial and operating performance and results; Viatris' or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal or other impediments to Viatris' ability to bring new products to market; products in development and/or that receive regulatory approval may not achieve expected levels of market acceptance, efficacy or safety; actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings on Viatris; any significant breach of data security or data privacy or disruptions to our IT systems; risks associated with international operations; 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 regarding future demand, pricing and reimbursement for the Company's products; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions, potential adverse impacts from future tariffs and trade restrictions, inflation rates and global exchange rates; 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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