Viatris Hosts R&D Event Focusing on its Collaboration with Idorsia, Phase 3 Assets Selatogrel and Cenerimod and Key Elements of its Pipeline

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PITTSBURGH, March 27, 2024 /PRNewswire/ -- At a meeting with the investment community today, Viatris Inc. (NASDAQ: VTRS), a global healthcare company, will outline how it is continuing to evolve its R&D strategy to deliver on its goal of building a more durable, higher-margin portfolio of patented innovation on the foundation of its strong base business. The focus of the event will be a discussion of its collaboration with Idorsia, Phase 3 assets selatogrel and cenerimod and key elements of the Company's pipeline.

Viatris CEO Scott A. Smith said: "Our confidence in our ability to continue to drive future growth and unlock shareholder value comes from our strong base business, well-established global infrastructure, and significant financial flexibility all of which give us the opportunity to continue to evolve our pipeline with the addition of potential blockbuster assets like selatogrel and cenerimod. The addition of high-science programs that deliver novel, meaningful patient impact and address significant unmet patient need will also give us the opportunity to accelerate long-term growth."

Event highlights will include:

- **Overview of global collaboration with Idorsia.** The collaboration with Idorsia is a great example of Viatris' strategy in action—adding two late-stage potential blockbuster assets, selatogrel and cenerimod—and connecting Idorsia's highly productive drug development team and innovation engine with Viatris' existing infrastructure and experience. The Company will review key elements of the collaboration including how Viatris can make a difference in the delivery of these assets.

- **The Company's history of development success.** Viatris' confidence is rooted in the strength of its base business, its deep in-house development capabilities, the diversity of its pipeline and its proven track record of scientific success, including a remarkable list of firsts that have enabled the Company to address some of the world's most enduring health challenges. The Company will review key highlights from its high-margin organic pipeline, which it expects will deliver $450 million to $550 million in revenue in 2024.

- **Overview of selatogrel.** Selatogrel, a potentially life-saving medicine, aims to become the first and only self-administered treatment for Acute Myocardial Infarction (AMI), or heart attack, by filling the medical gap between the onset of symptoms and hospitalization when early intervention is critical. The Company will review the pharmacological profile of selatogrel and the currently enrolling Selatogrel Outcome Study in suspected Acute Myocardial Infarction (SOS-AMI) global Phase 3 multi-center trial. This cardiovascular outcomes-based trial has received Special Protocol Assessment (SPA) agreement from the U.S. Food and Drug Administration (FDA) and selatogrel has received Fast-Track designation from the FDA.

- **Overview of cenerimod.** Cenerimod's novel mechanism of action has the potential to be a differentiated therapy for the treatment of Systemic Lupus Erythematosus (SLE), a chronic and progressive autoimmune disease in constant need of new treatment options that are safe and tolerable. The Company will review key learnings from the comprehensive Phase 2 program that has already been conducted and will review Oral S1P1 Receptor ModUlation in SLE (OPUS), the two ongoing Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies designed to evaluate cenerimod's efficacy, safety and tolerability in adult patients with moderate-to-severe SLE in addition to standard background therapy. Cenerimod has also received Fast-Track designation from the FDA.

2024 R&D Event Presenters
The event will feature presentations from the following Viatris executives:

- **Scott A. Smith**, Chief Executive Officer
- **Rajiv Malik**, President
- **Philippe Martin**, Chief R&D Officer
- **Doretta Mistras**, Chief Financial Officer

Expert thought leaders presenting at the event are:

- **Dr. Deepak L. Bhatt**, MD, MPH, MBA, FACC, FAHA, FESC, MSCAI, a top expert in cardiovascular medicine and interventional cardiology, is the Director of Mount Sinai Fuster Heart Hospital. Dr. Bhatt is highly recognized for his

significant breakthroughs in the field of cardiology, including interventional cardiology, heart disease prevention, vascular medicine and heart failure.

- **Dr. Anca Askanase**, MD, founder and clinical director of Columbia University's new Lupus Center and the Director of Rheumatology Clinical Trials. Dr. Askanase is an internationally renowned clinician, diagnostician and researcher with more than 15 years specializing in complex SLE. Dr. Askanase trained as a rheumatologist at New York University (NYU) where she remained for more than 15 years on faculty, directing clinical trials, training fellows and residents and treating challenging cases of SLE at NYU's prestigious hospitals.

Webcast Details
Interested parties will be able to access a live webcast of the event at investor.viatris.com. An archived version also will be available following the live event and can be accessed at the same location for a limited time.

About selatogrel
Selatogrel is a potent, fast-acting, reversible and highly selective P2Y12 inhibitor, being developed for the treatment of Acute Myocardial Infarction (AMI), in patients with a history of AMI. It is intended to be self-administered subcutaneously via a drug delivery system (autoinjector). This novel, self-administered emergency agent has the potential to protect heart muscle in the very early phase of an AMI – in the crucial time between symptom onset and first medical attention – so as to treat the ongoing AMI and prevent early death.

Viatris is enrolling patients into a large international, double-blind, randomized, placebo-controlled Phase 3 study – Selatogrel Outcome Study in suspected Acute Myocardial Infarction (SOS-AMI) – to assess the clinical efficacy and safety of selatogrel 16 mg when self-administered (on top of standard of care) upon the occurrence of symptoms suggestive of AMI. The primary efficacy endpoint is the occurrence of death from any cause, or non-fatal AMI, after self-administration of the study treatment.

A Special Protocol Assessment has been agreed with the FDA, indicating its concurrence with the adequacy and acceptability of critical elements of overall protocol design for a study intended to support a future marketing application. Selatogrel has received Fast-Track designation from the 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 cenerimod
Cenerimod is a highly-selective S1P1 receptor modulator given as an oral once-daily tablet. Cenerimod 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 S1P1 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 – for the first time in a lupus registration study – 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 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 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 how it is continuing to evolve its R&D strategy to deliver on its goal of building a more durable, higher margin portfolio of patented innovation on the foundation of its strong base business; its collaboration with Idorsia, Phase 3 assets selatogrel and cenerimod and key elements of the Company's pipeline; our confidence in our ability to continue to drive future growth and unlock shareholder value comes from our strong base business, well-established global infrastructure, and significant financial flexibility all of which give us the opportunity to continue to evolve our pipeline with the addition of potential blockbuster assets like selatogrel and cenerimod; the addition of high-science programs that deliver novel, meaningful patient impact and address significant unmet patient need will also give us the opportunity to accelerate long-term growth; the collaboration with Idorsia is a great example of Viatris' strategy in action—adding two late-stage potential blockbuster assets, selatogrel and cenerimod—and connecting Idorsia's highly productive drug development team and innovation engine with Viatris' existing infrastructure and experience; the Company's high-margin organic pipeline, which it expects will deliver $450 million to $550 million in revenue in 2024; information about selatogrel and cenerimod, information about clinical trials and studies; that a special protocol assessment has been agreed with the FDA, indicating its concurrence with the adequacy and acceptability of critical elements of overall protocol design for a study intended to support a future marketing application; selatogrel has received fast-track designation from the FDA; the investigation of cenerimod for the treatment of SLE has received fast-track designation from the FDA. 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 outcome of clinical trials and studies; 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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Contacts: MEDIA: +1.724.514.1968, Communications@viatris.com; Jennifer Mauer, Jennifer.Mauer@viatris.com; Matt Klein, Matthew.Klein@viatris.com; INVESTORS: +1.412.707.2866, InvestorRelations@viatris.com; Bill Szablewski, William.Szablewski@viatris.com