



ViatriS and Idorsia Enter Into Significant Global Research and Development Collaboration

February 28, 2024

- *Expands ViatriS' Portfolio of Innovative Assets by Immediately Adding Two Phase 3 Assets, Selatogrel and Cenerimod, Both With Blockbuster Revenue Potential*
- *Includes Future Optionality to Expand Collaboration With Additional Innovative Assets*
- *Combines ViatriS' Financial Strength and Worldwide Operational Infrastructure With Idorsia's Proven, Highly Productive Drug Development Team and Innovation Engine*
- *Deal Structure Reinforces ViatriS' Disciplined Approach to Capital Allocation*
- *ViatriS Announces R&D Event to be Held March 27, 2024*

PITTSBURGH, Feb. 28, 2024 /PRNewswire/ -- [ViatriS Inc.](#) (NASDAQ: VTRS), a global healthcare company, and Idorsia Ltd (SIX: IDIA) today announced they have entered into agreements for a significant global research and development collaboration under which ViatriS will receive exclusive global development and commercialization rights to two Phase 3 assets as well as the potential to add additional innovative assets in the future.

The collaboration includes selatogrel, a potential life-saving self-administered medicine for patients with a history of acute myocardial infarction (AMI), or heart attack, and builds on ViatriS' existing global cardiovascular franchise and specialty infrastructure, as well as its knowledge, leadership, and distribution capabilities for self-administered medication for acute life-threatening conditions.

The collaboration also includes cenerimod, a novel immunology asset that has the potential to be a first-in-class oral therapy for the treatment of systemic lupus erythematosus (SLE), the most common form of lupus. Through lifecycle management, this asset also has the potential for broad application across multiple autoimmune diseases in a specialist-driven category with attractive market dynamics for oral therapies and could be a cornerstone asset in ViatriS' immunology platform.

ViatriS CEO [Scott A. Smith](#) said: "I am extremely pleased with our global research and development collaboration with Idorsia. We are connecting Idorsia's proven, highly productive drug development team and innovation engine with ViatriS' strong global infrastructure and experience to focus on two late-stage potential blockbuster assets with long-dated patent protection. I believe that together we will be able to execute on the potential of these global assets, and any future assets, as we work to deliver on our goal of building a more durable, predictable portfolio on the foundation of our strong base business, and that selatogrel and cenerimod can become meaningful components of ViatriS' business over the long term.

Smith continued: "As I have said previously, in addition to continuing to develop the three core therapeutic areas that we identified—ophthalmology, dermatology and GI—we are also going to be opportunistic in seeking out assets that we believe fit our company well and have the potential to contribute significantly to our future revenue growth. Entering into this type of global research and development partnership structure with Idorsia is a great example of our disciplined approach to capital allocation."

ViatriS Chief R&D Officer Philippe Martin said: "I am excited to have the opportunity to work with Idorsia's talented drug development team who are essential to the execution of these clinical programs. Both selatogrel and cenerimod have the potential to be important medicines by providing significant advances for patients suffering with life-altering disease. Selatogrel has the potential to become the first self-administered treatment for recurring AMI that fills the medical gap during the pre-hospital phase of a life-threatening condition. Cenerimod has the potential to fill the need for a more tolerable and effective treatment for SLE, in combination with standard therapy, earlier in disease progression."

Idorsia CEO Jean-Paul Clozel, MD, said: "I'm delighted that with ViatriS we have found a strong partner to secure and accelerate the development programs for both selatogrel and cenerimod by leveraging the strength of ViatriS' global infrastructure. From the first meeting, it was clear that the team at ViatriS shares the same excitement and engagement for our innovations. This global collaboration allows us to share the costs of the ongoing Phase 3 programs whilst retaining long-term shareholder value, by sharing the rewards for success through the milestones and royalties."

Terms of the Transaction

Under the terms of the agreements, the development programs and certain personnel for selatogrel and cenerimod will be transferred to ViatriS in exchange for an upfront payment to Idorsia of \$350 million, potential development and regulatory milestone payments, and certain contingent payments of additional sales milestone payments and tiered royalties in the mid-single to low-double digit percentages on annual net sales. ViatriS and Idorsia will both contribute to the development costs for both programs. ViatriS will have worldwide commercialization rights for both selatogrel and cenerimod (excluding, for cenerimod only, Japan, South Korea and certain countries in the Asia-Pacific region) and intends to utilize its Global Healthcare Gateway® infrastructure to bring access to patients worldwide. A joint development committee will oversee the development of the ongoing Phase 3 programs through regulatory approval. The agreements also provide ViatriS a right of first refusal and a right of first negotiation for certain

other assets in Idorsia's pipeline. The closing of the transaction is subject to certain limited closing conditions, but no additional regulatory or shareholder approvals are required. The transaction is expected to close at the end of March.

Citi is acting as financial advisor to Viatriis.

R&D Event

Viatriis will hold an R&D Event on March 27, 2024, from 10 a.m. to noon ET, in New York City. The event will include presentations from Viatriis executives discussing the global research and development collaboration with Idorsia and other elements of the Company's pipeline, as well as presentations from two expert thought leaders. The presenters will be available to answer questions at the end of the presentations.

Expert thought leaders presenting at the event are:

- Dr. Deepak L. Bhatt, MD, MPH, a top expert in cardiovascular medicine and interventional cardiology, Director of Mount Sinai Heart. 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 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.

Interested parties will be able to access a live webcast of the event at investor.viatriis.com. An archived version 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.

Idorsia 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. In addition, the FDA designated the investigation of selatogrel for the treatment of suspected AMI as a "fast-track" development program. 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, the result of 20 years of research in Idorsia's labs, is a highly selective S1P₁ receptor modulator, given as an oral once-daily tablet. Cenerimod potentially offers a novel approach for the treatment of systemic lupus erythematosus (SLE), a disease with a significant impact on patients and limited treatment options.

In December 2022, Idorsia initiated the OPUS program (Oral S1P₁ Receptor ModUlation in SLE), 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 been designated as a "fast-track" development program by 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 Idorsia

Idorsia Ltd is reaching out for more – We have more ideas, we see more opportunities and we want to help more patients. In order to achieve this, we will develop Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a 20-year heritage of drug discovery, a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, and commercial operations in Europe and North America – the ideal constellation for bringing innovative medicines to patients.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 800 highly qualified specialists dedicated to realizing our ambitious targets.

About Viatriis

[Viatriis Inc.](https://www.viatriis.com) (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](https://www.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 Viatris and Idorsia entering into a significant global research and development collaboration; expanding Viatris' portfolio of innovative assets by immediately adding two Phase 3 assets, selatogrel and cenerimod, both with blockbuster revenue potential; includes future optionality to expand collaboration with additional innovative assets; combines Viatris' financial strength and worldwide operational infrastructure with Idorsia's proven, highly productive drug development team and innovation engine; deal structure reinforces Viatris' disciplined approach to capital allocation; R&D investor event to be held March 27, 2024; information about selatogrel and cenerimod; cenerimod could be a cornerstone asset in Viatris' immunology platform; we are connecting Idorsia's proven, highly productive drug development team and innovation engine with Viatris' strong global infrastructure and experience to focus on two late-stage potential blockbuster assets with long-dated patent protection; believe that together we will be able to execute on the potential of these global assets, and any future assets, as we work to deliver on our goal of building a more durable, predictable portfolio on the foundation of our strong base business, and that selatogrel and cenerimod can become meaningful components of Viatris' business over the long term; in addition to continuing to develop the three core therapeutic areas that we identified—ophthalmology, dermatology and GI—we are also going to be opportunistic in seeking out assets that we believe fit our company well and have the potential to contribute significantly to our future revenue growth; entering into this type of global research and development partnership structure with Idorsia is a great example of our disciplined approach to capital allocation; both selatogrel and cenerimod have the potential to be important medicines by providing significant advances for patients suffering with life-altering disease; selatogrel has the potential to become the first self-administered treatment for recurring AMI that fills the medical gap during the pre-hospital phase of a life-threatening condition; cenerimod has the potential to fill the need for a more tolerable and effective treatment for SLE, in combination with standard therapy, earlier in disease progression; the development programs and certain personnel for selatogrel and cenerimod will be transferred to Viatris in exchange for an upfront payment to Idorsia of \$350 million, potential development and regulatory milestone payments, and certain contingent payments of additional sales milestone payments and tiered royalties in the mid-single to low-double digit percentages on annual net sales; Viatris and Idorsia will both contribute to the development costs for both programs; Viatris will have worldwide commercialization rights for both selatogrel and cenerimod (excluding, for cenerimod only, Japan, South Korea and certain countries in the Asia-Pacific region) and intends to utilize its Global Healthcare Gateway® infrastructure to bring access to patients worldwide; a joint development committee will oversee the development of the ongoing Phase 3 programs through regulatory approval; the agreements also provide Viatris a right of first refusal and a right of first negotiation for certain other assets in Idorsia's pipeline; the closing of the transaction is subject to certain limited closing conditions, but no additional regulatory or shareholder approvals are required the transaction is expected to close at the end of March. 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 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; 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; 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 release other than as required by law.



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