Media Release
February 28, 2024

Ad hoc announcement pursuant to Art. 53 LR

Idorsia and Viatris enter into a significant global research and development collaboration

- Viatris and Idorsia will collaborate on the global development and commercialization of two Phase 3 assets, selatogrel and cenerimod.
- Idorsia to receive an upfront payment of USD 350 million, potential development and regulatory milestone payments, additional sales milestone payments and tiered royalties on annual net sales.
- Viatris and Idorsia will both contribute to the development costs for both programs.
- Includes future optionality to expand collaboration with additional pipeline assets.
- Combines Viatris' financial strength and worldwide operational infrastructure with Idorsia's proven, highly productive drug development team and innovative engine.

Allschwil, Switzerland – February 28, 2024
Idorsia Ltd (SIX: IDIA) today announced that it has entered into agreements for a significant global research and development collaboration with Viatris Inc. (NASDAQ: VTRS), a global healthcare company, for the global development and commercialization of two Phase 3 assets – selatogrel and cenerimod – for an upfront payment of USD 350 million, potential development and regulatory milestone payments, and certain contingent payments of additional sales milestone payments and tiered royalties from mid-single- to low double-digit percentage on annual net sales.

A joint development committee will oversee the development of the ongoing Phase 3 programs for selatogrel and cenerimod through regulatory approval. Idorsia will contribute up to USD 200 million in the next 3 years and will transfer to Viatris at closing the dedicated personnel to 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).

Idorsia has also granted Viatris a Right of First Refusal and First Negotiation for certain other pipeline assets.

The company expects to close the transaction by the end of March, subject to customary closing conditions, but no additional regulatory or shareholder approvals are required.

Jean-Paul Clozel, MD and Chief Executive Officer of Idorsia, commented:
"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."

Scott A. Smith, Chief Executive Officer of Viatris, commented:
"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."

André C. Muller, Chief Financial Officer of Idorsia, commented:
"In the coming weeks and months, we have many inflection points ahead, namely the FDA and CHMP decisions for aprocitentan, as well as expanded access and availability of QUVIVIQ (daridorexant) in the US, Canada and across Europe."

André continued:
"The upfront payment of USD 350 million gives us much needed liquidity. We've repeatedly explained that we have many balls in the air, we've now caught the first one and continue to work on others to secure Idorsia's future. We are working on several funding options, including business development opportunities, equity, and equity-linked deals to significantly extend our cash runway."

Notes to the editor

About selatogrel

Selatogrel is a potent, fast-acting, reversible, and highly selective $P2Y_{12}$ 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 $S1P_1$ 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 $S1P_1$ 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 compard 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 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).

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.

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