# Media Release
# January 11, 2021

## Idorsia to debut at the 39th J.P. Morgan Healthcare Conference – Major catalysts expected in the near-term – Daridorexant NDA submitted to the US FDA

- Daridorexant new drug application (NDA) submitted to the US Food & Drug Administration (FDA) on January 8, 2021

**Allschwil, Switzerland – January 11, 2021**
Idorsia Ltd (SIX: IDIA) today announced that Jean-Paul Clozel, Chief Executive Officer of Idorsia, will present at the 39th J. P. Morgan Healthcare Conference on January 12, 2021 at 09:10 Eastern Time / 15:10 Central European Time. The conference will take place fully virtual.

Jean-Paul will roll-out Idorsia's long-term vision and describe the progress made so far in delivering on the company priorities. He will also present why 2021 will be a key year for Idorsia with major catalysts expected in the near-term. Follow this link to access the audio stream of the presentation.

**Jean-Paul Clozel MD and Chief Executive Officer of Idorsia commented:**
"We are very pleased to give our first presentation at J.P. Morgan and introduce Idorsia to a new audience. Building on our 20-year heritage from Actelion, Idorsia is reaching out for more! We have one simple vision: creating a sustainable mid-size pharma company based on science and innovation. In just a few years, Idorsia has gone from strength to strength and 2020 saw the company making progress on all fronts – despite the COVID-19 pandemic."

**Highlights of 2020**
- Positive results in the Phase 3 program of daridorexant, demonstrating improved overall sleep and daytime functioning of patients with insomnia
- Positive results in the Japanese registration program for clazosentan, demonstrating a reduction in vasospasm-related morbidity and all-cause mortality
- US commercial operations established, with leadership team in place, and Syneos Health selected as commercialization partner to launch daridorexant in the US and effectively reach the primary care market
- Neurocrine Biosciences entered into a license agreement for the development and commercialization of Idorsia's novel T-type calcium channel blocker
- Successful capital increases secured over CHF 860 million of funding to prepare for the launch of daridorexant and to develop our diversified pipeline

**Jean-Paul commented on the 2020 achievements:**
"First and foremost, daridorexant gave outstanding results in insomnia both from an efficacy and safety perspective. Insomnia effects millions of people and there is no product that delivers on expectations of doctors or of the patients. Daridorexant has demonstrated improved nighttime sleep and, for the first time, improved daytime functioning, while keeping a favorable safety profile. Therefore, I truly believe that daridorexant can revolutionize the treatment of insomnia. Furthermore in 2020, the Japanese registration studies of clazosentan for patients suffering cerebral vasospasm also demonstrated excellent results. These are just two highlights from 2020, I'm very proud to say that – even in difficult circumstances – we reached every one of our ambitious goals set for the year."

**Milestones to look for in 2021**

- Daridorexant new drug application (NDA) submitted to the US FDA on January 8, 2021
- Filing of the daridorexant market authorization application (MAA) with the EMA
- Filing of the clazosentan NDA with the Japanese PMDA
- PDUFA for ponesimod in multiple sclerosis*
- Results of the registration study with lucerastat for Fabry disease
- Results of the safety & efficacy study with cenerimod for systemic lupus erythematosus
- Conclusion of recruitment of PRECISION with aprocitentan for difficult-to-control hypertension
- Initiation of Phase 3 study with selatogrel for suspected AMI

**Jean-Paul commented on the outlook for 2021:**
"2021 promises to be another exciting year for Idorsia. We begin with the excellent news that the team has finished compiling the vast amounts of data generated in the daridorexant development program and we have submitted the new drug application to the US FDA. Clearly, we have a laser focus on the filings and launch preparations for daridorexant in the US and EU, as well as clazosentan in Japan, but there is much more to come. This year will see the start of the large Phase 3 study with selatogrel for the emergency treatment of suspected heart attack and we will get more results from our late-stage studies with read-outs from the study of cenerimod for lupus, and the registration study with lucerastat for Fabry disease in the second half of the year."

**Jean-Paul concluded:**
"Our previous endeavors demonstrate that we know what it takes to successfully bring drugs from the lab bench to the patients' bedside and we have all the ingredients needed to succeed: A team that is second to none, a powerful drug discovery engine and rich pipeline, a global expert commercial organization, and strong liquidity. We have already delivered incredible results in our short history, but this is just the beginning of creating a very exciting company. So, be prepared for more!"

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## Notes to the editor

***About the Revenue Sharing Agreement for ponesimod**
Idorsia and Actelion Pharmaceuticals Ltd, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, have entered into a revenue-sharing agreement in respect to ponesimod. Under the terms of the revenue-sharing agreement, Idorsia is entitled to receive quarterly payments of 8% of the net sales of ponesimod products from Actelion Pharmaceuticals Ltd.

**About the Phase 3 program with daridorexant**
In April and July of 2020, Idorsia reported positive results in each of the two pivotal Phase 3 studies of daridorexant in patients with insomnia. More details and commentary can be found in the dedicated press releases (first study release), (second study release) and the investor webcasts (first study webcast), (second study webcast) which are available for replay on Idorsia's corporate website: www.idorsia.com

**About the Japanese registration program with clazosentan**
In November of 2020, Idorsia reported positive results in each of the two Japanese registration studies of clazosentan in patients with cerebral vasospasm following aneurysmal subarachnoid hemorrhage. More details can be found in the dedicated press release.

## 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 one of Europe's leading biopharmaceutical companies, with a strong scientific core.

Headquartered in Switzerland - a biotech-hub of Europe - Idorsia is specialized in the discovery and development of small molecules, to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team, a fully-functional research center, and a strong balance sheet – the ideal constellation to bringing R&D efforts to business success.

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.

## For further information, please contact

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